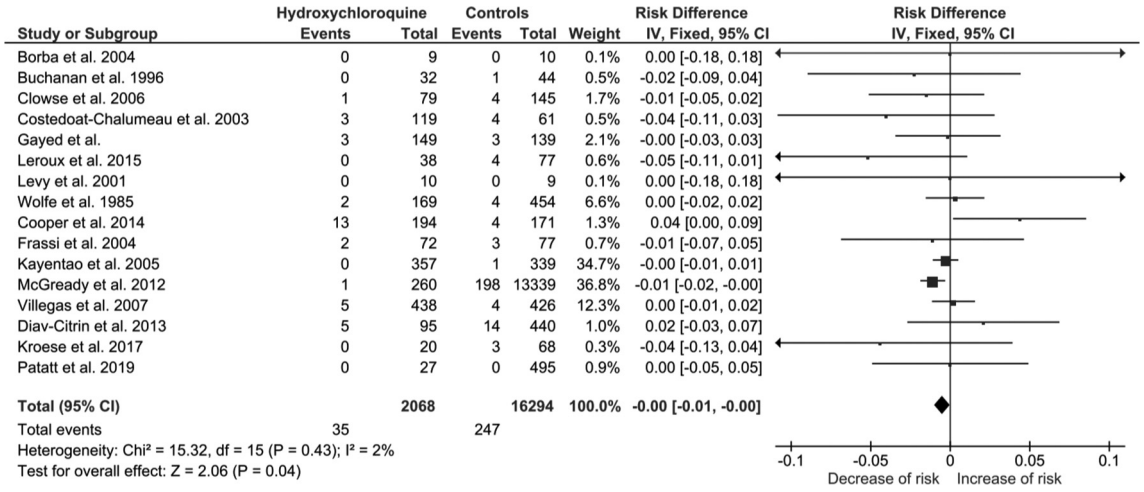


Abstract O7 Figure 1 Forest plot of the malformation rates comparing CQ/HCQ treated group vs. non-treated controls

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

[1]Martin Aringer, [2]Ralph Brinks, [3]Karen Costenbader, [4]Dimitrios Boumpas, [5]David Daikh, [6]David Jayne, [7]Diane L Kamen, [8]Marta Mosca, [9]Rosalind Ramsey-Goldman, [10]Josef S Smolen, [11]David Wofsy, [12]Betty Diamond, [13]Søren Jacobsen, [14]W Joseph McCune, [15]Guillermo Ruiz-Irastorza, [16]Matthias Schneider, [17]Murray Urowitz, [18]George Bertsias, [19]Bimba Hoyer, [20]Nicolai Leuchten, [21]Chiara Tani, [22]Sara K Tedeschi, [23]Zahi Touma, [24]Branimir Anic, [25]Florence Assan, [26]Tak Mao Chan, [27]Ann E Clarke, [28]Peggy Crow, [29]Lazlo Czirjak, [30]Andrea Doria, [31]Winfried Graninger, [32]Bernadette Halda-Kiss, [33]Sarfaraz A Hasni, [34]Peter M Izmirly, [35]Michelle Jung, [32]Gabor Kumanovics, [25]Xavier Mariette, [24]Ivan Padjen, [36]JM Pego-Reigosa, [37]Juanita Romero-Díaz, [38]Iñigo Rúa-Figueroa, [39]Raphaele Seror, [40]Georg Stummvoll, [41]Yoshiya Tanaka, [4]Maria Tektonidou, [42]Carlos Vasconcelos, [43]Edward M Vital, [44]Daniel J Wallace, [45]Sule Yavuz, [46]Raymond P Naden, [47]Thomas Dorner, [48]Sindhu Johnson. *[1]Medicine III, University Medical Center and Faculty of Medicine at the TU Dresden, Dresden; [2]Dept. of Rheumatology and Hiller Research Unit, Heinrich-Heine University, Düsseldorf, Germany; [3]Rheumatology, Immunology and All, Brigham and Women's Hospital, Boston, USA; [4]University of Athens, Athens, Greece; [5]Rheumatology, UCSF/VA Medical Center, San Francisco, USA; [6]Dept. of Medicine, University of Cambridge, Cambridge, UK; [7]Medicine/Rheumatology and Immunology, Medical University of South Carolina, Charleston, USA; [8]Rheumatology Unit, University of Pisa, Pisa, Italy; [9]FSM, Northwestern University, Chicago, USA; [10]Devision of Rheumatology, Dept. of Medicine 3, Medical University of Vienna, Vienna, Austria; [11]University of California San Francisco, San Francisco; [12]Autoimmune Musculoskeletal and Hematopoietic Diseases, The Feinstein Institute, Manhasset, USA; [13]University of Copenhagen, Copenhagen, Denmark; [14]Int Med/Rheum, University of Michigan, Ann Arbor, USA; [15]Autoimmune Diseases Research Unit, BioCruces, Hospital Universitario Cruces, Baracaldo, Spain; [16]Dept. and Hiller Research Center for Rheumatology, University Hospital Duesseldorf, Duesseldorf, Germany; [17]Centre for Prognosis Studies in the Rheumatic Diseases, University of Toronto, Toronto Western Hospital, Toronto, Canada; [18]University of Crete, Heraklion, Greece; [19]University of Schleswig-Holstein, Kiel; [20]University Medical Center and Faculty of Medicine TU Dresden, Dresden, Germany; [21]University of Pisa, Pisa, Italy; [22]Rheumatology Immunology and Allergy, Brigham and Women's Hospital, Boston, USA; [23]Rheumatology, University of Toronto, Division of Rheumatology, Institute of Health Policy, Management and Evaluation, Toronto, Canada; [24]University Hospital Zagreb, Zagreb, Croatia; [25]Université Paris Sud, Paris, France; [26]University of Hong Kong, Hong Kong; [27]Division of Rheumatology, University of Calgary, Calgary, Canada; [28]Dept. of Medicine, Hospital for Special Surgery, New York, USA; [29]Dept. of Rheumatology and Immunology, University of Pécs, Pécs, Hungary; [30]University and Azienda Ospedaliera of Padova, Padova, Italy; [31]Rheumatology and Immunology, Medical University of Graz, Graz, Austria; [32]University of Pécs, Pécs, Hungary; [33]Lupus Clinical Research Program, Office of the Clinical Director, NIH/NIAMS, Bethesda; [34]New York University School of Medicine, New York, USA; [35]University of Calgary, Calgary, Canada; [36]Rheumatology Section, Hospital de Meixoeiro, Pontevedra, Vigo, Spain; [37]Immunology and Rheumatology, Instituto Nacional de Ciencias Medicas y Nutricion, Mexico City, Mexico; [38]Rheumatology Division, Hospital Doctor Negrin, Las Palmas GC, Spain; [39]Center for Immunology of Viral Infections and Autoimmune Diseases, Assistance Publique – Hôpitaux de Paris, Hôpitaux Universitaires Paris-Sud, Le Kremlin-Bicêtre, Université Paris Sud, INSERM, Paris, France; [40]Rheumatology, Medical University Vienna, Vienna, Austria; [41]First Dept. of Internal Medicine, University of Occupational and Environmental Health, Kitakyushu, Japan; [42]University of Porto, Porto, Portugal; [43]University of Leeds, Leeds, UK; [44]Division of Rheumatology, Cedars-Sinai Medical Center, Los Angeles, USA; [45]Dept. of Rheumatology, Marmara University, Istanbul, Turkey; [46]New Zealand Ministry of Health, New Zealand Ministry of Health, Auckland, New Zealand; [47]Charité Universitätsmedizin Berlin, Berlin, Germany; [48]Rheumatology, Mount Sinai Hospital and University Health Network, Toronto, Canada*

10.1136/lupus-2020-eurolupus.21

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

Abstract O8 Table 1

	N	EULAR/ACR 2019 Criteria		ACR 1997 Criteria		SLICC 2012 Criteria	
		Sensitivity	Specificity	Sensitivity	Specificity	Sensitivity	Specificity
	1,270	**0.96**	**0.93**	**0.83**	**0.93**	**0.97**	**0.84**
95% CI		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.

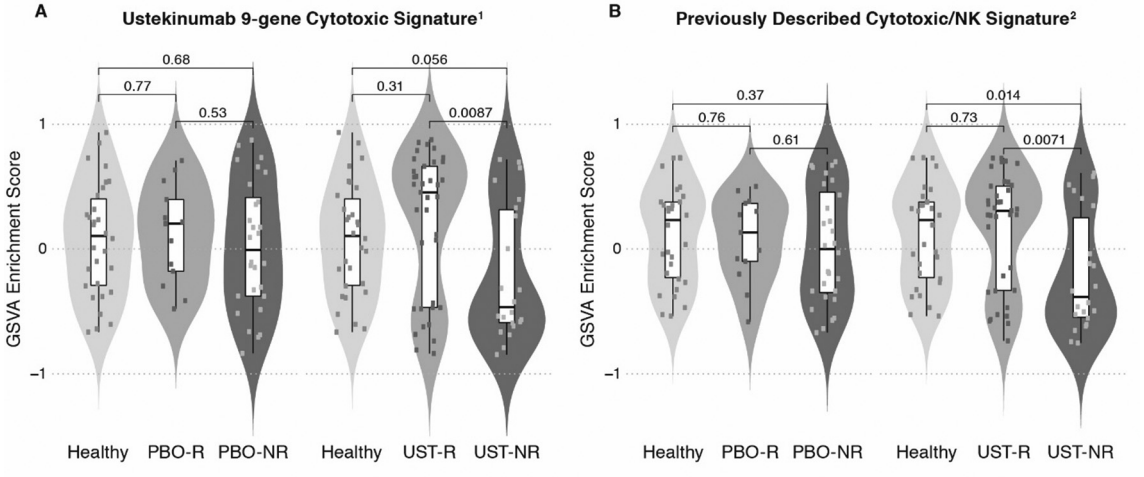
Conclusion While not all subgroups of SLE patients in the validation cohort are of adequate size to fully explore the sensitivity and specificity of the EULAR/ACR 2019 SLE classification criteria in the respective subsets, the point estimates of sensitivity and specificity suggest that the new criteria 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.

O9 REDUCTION OF INTERFERON-γ AND ELEVATED BASELINE CYTOTOXIC GENE EXPRESSION IN THE BLOOD ASSOCIATE WITH USTEKINUMAB RESPONSE IN SLE

[1]Loqmane Seridi, [1]Matteo Cesaroni, [1]Matt Loza, [1]Jessica Schreiter, [1]Kristen Sweet, [1]Kim Campbell, [2]Peter Lipsky, [3]Ronald van Vollenhoven, [4]Bevra H Hahn, [5]George C Tsokos, [1]Marc Chevrier, [1]Shawn Rose, [1]Frédéric Baribaud, [1]Jarrat Jordan. *[1]Janssen Research and Development, Spring House; [2]AMPEL BioSolutions, Charlottesville, USA; [3]Amsterdam Rheumatology and Immunology, Amsterdam, The Netherlands; [4]UCLA, Los Angeles; [5]Harvard Medical School, Boston, USA*

10.1136/lupus-2020-eurolupus.22

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



1. Seridi L, Cesaroni M, Loza M, et al. Baseline Cytotoxic Gene Expression Associates with Ustekinumab Response in Systemic Lupus Erythematosus [abstract]. ***Arthritis Rheumatol*** 2019; 71 (suppl 10). https://acrabstracts.org/abstract/baseline-cytotoxic-gene-expression-associates-with-ustekinumab-response-in-systemic-lupus-erythematosus/. Accessed October 17, 2019.
2. Banchereau R, Hong S, Cantarel B, et al. Personalized Immunomonitoring Uncovers Molecular Networks that Stratify Lupus Patients. ***Cell*** 2016;165:1548-1550.

2694_v2

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