Mean PROMIS T Score of All Patients in Interim Analysis Dataset and a Comparison of T Scores of PROMIS-29 Domains, Fatigue Short Form and Pain Interference Short Form to CDAI Disease Activity Category

	All Patients (n=353)	Remission CDAI</=2.8 (n=3)	LDA 2.8<CDAI</=10 (n=13)	MDA 10<CDAI</=22 (n=78)	HDA CDAI>22 (n=259)
P29-Physical Function	37.5 ± 6.4	50.1 ± 6.07	43.5 ± 7.37	39.7 ± 6.83	36.4 ± 5.66*
P29-Anxiety	54.5 ± 10.3	44.8 ± 7.74	50.4 ± 9.12	51.6 ± 10.0	55.7 ± 10.24*
P29-Depression	52.7 ± 10.1	43.7 ± 4.62	46.2 ± 7.25	49.8 ± 10.18	54.0 ± 9.91*
P29-Fatigue	59.9 ± 9.6	41.8 ± 7.53	51.1 ± 9.57	56.9 ± 9.55	61.5 ± 9.04*
P29-Sleep Disturbance	56.0 ± 8.3	52.8 ± 14.36	52.3 ± 6.41	54.1 ± 8.48	56.8 ± 8.17
P-29 Ability to participate in Social Roles and Activities	42.3 ± 8.2	56.2 ± 9.18	49.9 ± 8.43	44.5 ± 8.84	41.2 ± 7.50*
P29-Pain Interference	64.0 ± 7.5	45.7 ± 7.1	54.3 ± 7.81	61.0 ± 8.10	65.5 ± 6.35*
Fatigue SF 7a	60.3 ± 8.3	43.0 ± 10.19	54.3 ± 7.65	57.5 ± 7.22	61.7 ± 8.02*
Pain Interference SF 6b	63.0 ± 7.7	43.5 ± 4.33	54.6 ± 9.29	59.9 ± 8.03	64.5 ± 6.62*
P29 Pain Intensity (scored 0-10 scale)	6.2 ± 2.2	2.0 ± 3.46	3.5 ± 1.71	5.4 ± 2.32	6.6 ± 1.91*

T scores > 50 indicate worsening of the domain relative to the general population, except "Physical Function" and "Ability to participate in Social Roles and Activities", where T-scores < 50 indicate worsening of these domains relative to the general population. * = p<0.05 vs respective scores in MDA, LDA and remission DA categories

Conclusions: These interim data further support the viability of using PROMIS questionnaires to evaluate RA pts, and indicate in this predominantly HDA population of RA pts correlations between PROMIS and CDAI disease activity category. Confirmation of the baseline interim analysis findings with the fully enrolled AWARE study, as well as inclusion of longitudinal and subset analyses based on disease activity levels, will further define the role of PROMIS relative to CDAI in RA patients in a real world setting.

Disclosure of Interest: J. Curtis Consultant for: Janssen, AbbVie, Roche/Genentech, BMS, UCB, Myriad, Lilly, Amgen, Pfizer, Corrona, S. Kafka Employee of: Janssen Scientific Affairs, LLC, D. Parenti Employee of: Janssen Scientific Affairs, LLC, S. Black Employee of: Janssen Scientific Affairs, LLC, S. Xu Employee of: Janssen Research & Development, LLC, Y. Wang Employee of: Janssen Research & Development, LLC, C. Bingham III Grant/research support from: Janssen, PCORI, NIH, Pfizer, Consultant for: Janssen, AbbVie, Amgen, BMS, Celgene, Genentech/Roche, Lilly, Macrogenics, Meoblast, Novartis, NovoNordisk, Pfizer, Regeneron, UCB

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THU0673 THE EUROPEAN CONSENSUS FINDING STUDY GROUP (ECFSG) HELPS CHARACTERIZING NEW TENTATIVE REFERENCE STANDARDS FOR AUTOANTIBODY MEASUREMENT

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Background: Since 1988, the European Consensus Finding Study Group on autoantibodies in rheumatic diseases (ECFSG), also known as the EULAR autoantibody study group, has been distributing sera with unspecified antibodies to European laboratories (presently n=43) for evaluation of different autoantibody measurement techniques in a clinical context. Use of reference materials helps to align test results by adopting internationally used measurement units, but reference materials are missing for many autoantibody specificities.

Objectives: Recently the scope for ECFSG was expanded to also include unbiased autoantibody characterization of serum/plasma specimens planned to constitute raw material for production of future autoantibody reference materials.

Methods: Four samples were included to be evaluated as future tentative international reference materials for four different autoantibody specificities: double stranded/native DNA (dsDNA, evaluated in 2013/14), IgG anti-b2GP1, proteinase 3 (PR3) and myeloperoxidase (MPO, evaluated in 2015/16). The samples were included "blind", and evaluated broadly for multiple autoantibody specificities by participating laboratories.

Results: All or almost all participating laboratories detected the target specificities, and all four samples showed restricted autoantibody specificities related to the target specificity. Anti-dsDNA was detected by all laboratories using *Crithidia luciliae*, ELISA/EIA, FARR assay or ALBIA and all labs reported a homogenous ANA pattern. Other specificities were restricted to histones, nucleosomes and anti-Ku. All laboratories but one detected IgG anti-b2GP1 and IgG anti-cardiolipin, mostly in high levels, in the tentative IgG anti-b2GP1 reference standard, whereas corresponding IgA and IgM antibodies were absent. All laboratories detected anti-MPO, mostly monospecific and in high levels together with P-ANCA pattern in the anti-MPO reagent. Anti-PR3 and C-ANCA pattern, mostly in high levels/titers were detected by all laboratories in the tentative anti-PR3 reagent, irrespective of method used.

Conclusions: The expanded scope of ECFSG has enabled broad characterization of new tentative autoantibody reference standards. The anti-dsDNA specimen has been processed by the National Institute for Biological Standards and Control (NIBSC) for consideration as the 2nd WHO anti-dsDNA reference standard. The other materials are basis for certified reference material for IgG anti-myeloperoxidase (ERM-DA476/IFCC), and the candidate reference materials for IgG anti-proteinase 3 (in certification) and for IgG anti-b2PG1 (in evaluation) from the Joint Research Centre.

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THU0674 ANTI-DFS70 ANTIBODY – A BIOMARKER THAT AID IN THE EXCLUSION OF ANA ASSOCIATED RHEUMATIC DISEASES

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Background: Positive ANA may lead to additional testing and potentially even inappropriate treatment in patients with rheumatic symptoms not caused by ANA associated rheumatic diseases (AARD).

Objectives: It has been shown that autoantibodies directed against lens epithelial derived growth factor (LEDGF), also named DFS70 according to the staining pattern (dense fine speckled) and molecular weight of the target antigen (70 kDa), are common among ANA positive individuals with no evidence of AARD [1,2]. The aim of our study was to evaluate if autoantibodies directed against DFS70 can be used to exclude AARD in ANA positive patients.

Methods: Anti-DFS70 antibody were determined by chemoluminescence assay (CIA) in sera of 352 apparently healthy controls (AHI), 1048 patients of an ANA positive routine cohort, 579 patients with AARD (300 SLE, 76 idiopathic inflammatory myopathies, 167 systemic sclerosis, 36 Sjögren's syndrome), 56 patients with undifferentiated connective tissue disease (UCTD), and 660 non-AARD patients (302 rheumatoid arthritis, 94 ANCA-associated vasculitis, 87 atopic rhinitis, 135 pediatric patients with celiac disease, and 42 autoimmune liver diseases).

Results: In AHI and in the non-AARD cohort, anti-DFS70 antibodies occur with a prevalence of 5.1% and 2%, respectively. Of the 1048 selected routine sera, 205 (19.6%) were positive for anti-DFS70 antibodies. Up to now, clinical reports are available for 116 of anti-DFS70 positive patients in this group. The diagnoses were widely scattered (nonspecific rheumatic symptoms, arthritis, thyreoiditis, asthma, psoriasis, tumor, infections, inflammatory bowel disease), but no definite AARD could be diagnosed. In the AARD group, only 6 of 579 patients (1.2%) were positive for anti-DFS70 antibodies, all of them also show disease specific autoantibodies (two anti-Scl70 antibody positive SSc, one anti-RNAPIII antibody positive SSc, one Ro-52 positive SSc, one anti-Mi-2 antibody positive IIM, one SLE patient with multiple autoantibodies including dsDNA antibodies). In patients with UCTD, 6 (10.7%) were anti-DFS70 antibody positive in the absence of disease specific autoantibodies. Up to now, no development of an AARD was observed in these patients.

Conclusions: Anti-DFS70 antibodies are frequently observed in sera with chromatin binding antibodies in the absence of disease specific autoantibodies. If anti-DFS70 antibodies are positive in the absence of AARD specific autoantibodies, an AARD can be excluded with high certainty.

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THU0675 DEVELOPMENT AND PSYCHOMETRIC VALIDATION OF A TOOL TO ASSESS THE FEARS OF PATIENTS WITH CHRONIC INFLAMMATORY RHEUMATIC DISEASES: THE FAIR SCALE

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Background: Patients (pts) with chronic inflammatory rheumatic diseases (CIRDs) such as rheumatoid arthritis (RA) and axial spondyloarthritis (axSpA) have fears related to their disease that can negatively impact health-related quality of life and compromise treatment adherence.

Objectives: To develop and validate a patient-reported outcome (PRO) ques-