

strongly with JIA disease activity (table 2). Among parent proxy CATs, only anxiety correlated with disease activity ( $r=0.71$ ); however the association was not statistically significant.

Table 1 Patient characteristics

Characteristic	N=26 patients
Age, years, median [IQ range]	12.7 [6.0, 14.5]
Male	8 (30.8%)
White or Caucasian	20 (76.9%)
Insurance	
Medicaid	6 (23.1%)
Device	
Smartphone	18 (69.2%)
iPad	3 (11.5%)
Location	
In hospital	8 (30.8%)
Remotely	18 (69.2%)

Table 2 Spearman correlation coefficients for PROMIS domains and JADAS71 score

PROMIS domain	JADAS71 score Spearman correlation coefficient
<b>PATIENT SCORES</b>	
Fatigue T-score	0.488
<b>Pain Interference T-score</b>	<b>0.640</b>
Peer Relations T-score	-0.345
<b>Anxiety T-score</b>	<b>0.738</b>
<b>Depressive Symptoms T-score</b>	<b>0.840</b>
Mobility T-score	-0.671

**Conclusions:** Our results demonstrate that the PROMIS CATs are feasible to administer in an outpatient pediatric rheumatology setting. Anxiety, depressive symptoms, and pain interference were significantly correlated with disease activity, even though mean disease activity was relatively low. This underscores the negative effect on quality of life of even mild disease. Parent proxy CATs showed poor correlations with disease activity, suggesting parents are inaccurate in assessing important aspects of their child's health. Larger prospective studies are needed to evaluate the sensitivity of PROMIS CATs to change in disease activity over time.

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### FRI0674 APPLICABILITY OF THE PSAID12 QUESTIONNAIRE AS A CORE OUTCOME MEASUREMENT IN PSA CLINICAL TRIALS: AN EVALUATION USING OMERACT FILTER 2.1 INSTRUMENT SELECTION CRITERIA

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**Background:** The Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA)–Outcome Measures in Rheumatology (OMERACT) Psoriatic Arthritis (PsA) Core Set working group is in the process of selecting core outcome measurements for PsA randomised trials, following OMERACT Filter 2.1 for instrument selection<sup>1</sup>. The Psoriatic Arthritis Impact of Disease questionnaire (PsAID12) passed the first two steps (domain match and feasibility) at the GRAPPA 2017 annual meeting and is a candidate instrument to measure PsA specific health related quality of life (HRQOL)/Life impact.

**Objectives:** To conduct a systematic review (SR) of the PsAID literature to review the measurement properties in the OMERACT Filter 2.1, assess specifically construct validity (truth) and discrimination of the PsAID12 questionnaire based on available evidence, and to identify gaps in knowledge that need to be covered in order for PsAID12 to pass Filter 2.1.

**Methods:** A SR of PsA patient reported outcomes (PROs) was performed January 1 2017 and updated by hand search (22/11/2017). All articles assessing the measurement properties of the PsAID12 were reviewed. Strength of evidence was rated using COSMIN-OMERACT Good Methods checklist, and performance of measurement properties using the OMERACT standards<sup>1</sup>. We extracted data on domain match (face and content validity), construct validity, test-retest reliability, longitudinal construct validity, clinical trials discrimination, and thresholds of meaning.

**Results:** We identified six studies (129–474 patients in each study) assessing the measurement properties of the PsAID12 in adults with PsA. Domain match: PsAID12 was developed with 12 patient research partners, 139 patients who ranked domain importance and cognitive interviews with 65 patients. Construct validity: Three studies assessed correlation of the PsAID12 with PROs and clinical outcomes, and one study with two PROs. There was strong correlation with measures of function ( $n=3$  studies,  $r>0.66$ ), participation (1,  $r>0.69$ ), disease

activity (2,  $r=0.64–0.87$ ), and measures of pain, fatigue and stiffness (1 each,  $r>0.83$ ); moderate-strong with patient and physician global (3,  $r=0.49–0.84$ ); and moderate with 66/68 joint counts (1,  $r=0.4–0.57$ ) and dactylitis (1,  $r=0.49$ ). Test-retest reliability was high (0.91 (95%CI 0.87–0.94) and 0.95 (0.92–0.96)). Longitudinal construct validity was good with moderate to large standardized response mean (SRM) 0.74 ( $n=53$ , changed therapy) and 0.91 ( $n=71$ , changed therapy and rated themselves improved). The patient acceptable symptom state (PASS) was 4 in a single study. The minimal clinically important improvement (MCII) varied between 3 (original PsAID development study) and 1.25 (subsequent UK study).

**Conclusions:** This review suggests there is evidence for excellent content validity and reliability and good construct validity and responsiveness of the PsAID12 questionnaire as a measure of HRQOL in PsA. MCII and discrimination in clinical trials need to be defined.

### REFERENCE:

- Boers M, Kirwan JR, Tugwell P, et al. The OMERACT Handbook. Accessed 5 January 2018, <https://www.omeract.org/resources>

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### FRI0675 RABIOFPRED, AN INNOVATIVE THERANOSTIC TOOL TO ASSIST CLINICIANS SELECT AN OPTIMAL ANTI-TNF ALPHA BIOLOGICAL THERAPY FOR RHEUMATOID ARTHRITIS PATIENTS

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**Background:** TNF alpha blockers form 2nd line treatment choice for Rheumatoid Arthritis (RA) patients. Up to 30% of RA patients do not respond to TNF alpha blockers for unknown reasons, causing a significant impact on patients' outcome and healthcare industry. Therefore, there is an unmet need for a tool to predict treatment response that could help clinicians to choose an optimal treatment for RA patients.

**Objectives:** By using Immuno-Detect, an innovative targeted gene sequencing panel of 2155 mRNA targets associated with immune-inflammatory pathways, we aimed to develop an algorithm, RABIOFPRED, that predicts non-response to TNF alpha blockers.

**Methods:** Paxgene samples obtained at baseline from 68 patients naïve to TNF alpha blockers were directly profiled without extraction with Immuno-Detect panel on HTG EdgeSeq platform, a combination of a nuclease protection assay & next generation sequencing (NGS). Patients were treated with Infliximab, Etanercept or Adalimumab and disease activity score was measured based on DAS28 score at 3 months. Response to treatment was assessed by categorizing the patients according to EULAR response criteria. Gene combinations were selected using variable importance score (VIS). Predictive modeling performance was evaluated using the area under the curve (AUC) and confusion matrix.

**Results:** Analytical validation of Immuno-Detect panel shows a very high reproducibility on Paxgene and extracted RNA samples with correlation factor of 0.975 and 0.96 respectively. In paxgene samples, among 2155 genes, 1172 mRNAs are significantly expressed with a mean CV of 9.77% (976 mRNAs and mean CV of 11.98% for RNA). Most expressed target represent only 5% of the total reads and only 20 targets are reaching 1% of total reads showing a very well balanced panel. Performance of our predictive model shows an AUC of 0.905 with 0.88 accuracy. Our algorithm predicts non-responders to TNF alpha blockers with the sensitivity of 0.78 and positive predictive value of 0.91. This algorithm will be further validated within the ongoing RABIOFPRED Proof-of-Performance study (ClinicalTrials.gov Identifier: NCT03016260) based on 720 patients treated by anti-TNF alpha drugs (5 originators & 3 biosimilars) launched in December 2016.

**Conclusions:** We are showing that Immuno-Detect panel accurately measures mRNA expression using HTG-EdgeSeq NGS platform. This panel can be further used to build signatures to predict TNF alpha blocker's non-response. The algorithm obtained in the current study will be later on validated in a multi-centric proof-of-performance clinical study.

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FRI0676

### RESPONSIVENESS OF PATIENT REPORTED OUTCOMES MEASUREMENT INFORMATION SYSTEM (PROMIS®) COMPUTERIZED ADAPTIVE TESTS (CATS) IN SYSTEMIC LUPUS ERYTHEMATOSUS (SLE)

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**Background:** The accurate measurement of patient reported outcomes is a priority for patient-centered care in SLE, a chronic systemic disease with significant impact on quality of life. PROMIS CATs are precise measures of physical, mental, and social health with construct validity in SLE. The longitudinal responsiveness (sensitivity to change) of PROMIS CATs in SLE patients is unknown.

**Objectives:** To evaluate the responsiveness of PROMIS CATs in SLE outpatients using patient and physician-derived anchors.

**Methods:** Adult SLE patients were recruited from an SLE Center of Excellence. Subjects completed 14 selected PROMIS CATs at two visits a minimum of one month apart. SLE disease activity was measured with a patient global assessment of change, a physician global assessment and the physician-derived SELENA-SLEDAI. Responsiveness of PROMIS scores was evaluated using known-groups validity. Effect sizes were compared across groups of patients who differed in their patient global assessment of change, physician global assessment, and SELENA-SLEDAI using Wilcoxon rank-sum tests.

**Results:** A diverse cohort of 228 SLE patients, including 45 (19.8%) patients flaring by SELENA-SLEDAI, completed baseline surveys. Follow up surveys were completed by 190 (83%). There was poor agreement between patient and physician global assessments (weighted kappa statistic [95% CI]=0.16 [0.04–0.28]. Using the patient-based anchor, Anger, Pain Interference, and Physical Function CATs showed low to moderate responsiveness (table 1). Using the physician global assessment, only Anxiety CAT showed low to moderate responsiveness (effect size -0.27, -0.17, and 0.06 [p=0.03] with ≥0.5 point decrease, <0.5 point change, and ≥0.5 point increase respectively), while with the SELENA-SLEDAI as anchor, only Applied Cognition-Abilities CAT showed responsiveness (0.34, -0.01, 0.0 [p<0.01] with ≥3 point decrease, <3 point change, and ≥3 point increase respectively).

PROMIS CAT	Patient Global Assessment of Change			p-value
	Better (n=74)	Same (n=79)	Worse (n=33)	
Ability to Participate in Social Roles	0.14	0.00	0.00	0.19
<b>Anger</b>	<b>-0.37</b>	<b>-0.08</b>	<b>0.00</b>	<b>0.03</b>
Anxiety	-0.38	-0.04	-0.02	0.13
Applied Cognition-Abilities	0.15	0.00	-0.03	0.30
Applied Cognition-General Concerns	-0.08	0.00	-0.06	0.47
Depression	-0.15	0.00	0.36	0.15
Fatigue	-0.16	0.00	-0.15	0.51
Mobility	0.14	0.00	0.00	0.26
Pain Behavior	-0.14	0.00	0.10	0.07
<b>Pain Interference</b>	<b>0.00</b>	<b>0.00</b>	<b>0.25</b>	<b>0.02</b>
<b>Physical Function</b>	<b>0.15</b>	<b>0.01</b>	<b>-0.14</b>	<b>0.02</b>
Satisfaction with Social Roles & Activities	0.18	0.00	0.00	0.21
Sleep Disturbance	0.00	-0.14	-0.04	0.50
Sleep-Related Impairment	-0.07	0.00	-0.02	0.95

**Conclusions:** PROMIS CATs showed modest responsiveness to patient-reported, but generally not physician-derived changes in lupus health status in domains of anger, pain interference, and physical function. These data suggest that certain PROMIS CATs are precise and sensitive tools which may be used to measure and monitor important aspects of the patient experience of lupus not captured by physician-derived metrics. Further studies are needed to evaluate the responsiveness of PROMIS CATs in populations with greater SLE disease activity and more regular follow up.

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FRI0677

### PREVALENCE AND SEROLOGICAL PROFILE OF ANTI-DFS70 POSITIVE SUBJECTS: DATA FROM A ROUTINE ANA COHORT

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**Background:** Anti-Dense Fine Speckled 70 (DFS70) antibodies are a common finding in clinical laboratory referrals. High prevalence of DFS70 autoantibodies in

healthy population and usual negative association with Antinuclear Antibody (ANA)-associated autoimmune rheumatic diseases were reported.

**Objectives:** The aim of this study was to evaluate the prevalence of anti-DFS70 antibodies in a routine diagnostic laboratory setting and their association with other circulating serum autoantibodies.

**Methods:** Consecutive sera submitted for ANA screening were analyzed for anti-DFS70 antibodies by indirect immunofluorescence (IIF) (n=3175, 1030 men and 2145 women) then confirmed by Immunoblotting. IIF DFS70 positive adult patients were recruited previous written consent and tested for the following autoantibodies: anti-ENA, anti-dsDNA, -anti-TPO, anti-TG, anti-tTG, aCL, anti-PCA, AMA, ASMA, anti-LKM, anti-MPO, anti-PR3 and ASCAs.

**Results:** The prevalence of anti-DFS70 antibodies was 1.7% (n= 55) in the whole population and 4.6% in the ANA-positive samples. Comparison between DFS70 IIF and Immunoblotting showed an excellent correlation between the two methods (R=0.99). Analysis of anti-DFS70 antibodies titers distribution revealed that 63% of the total cohort showed high titers (≥1:640). Gender difference (female: male, 4:1) was observed in anti-DFS70 positive group and in anti-DFS70 negative/ANA positive group. The prevalence of anti-DFS70 positive female (2.1%, 45/2145) was statistically significant higher than males (1.0%, 10/1030) (p<0.05). The comparison among referring sources evidenced a prevalence of anti-DFS70 positive subjects from Endocrinology Department (9.1% versus 2.6% from Haematology, 2.1% from outpatients, 1.6% from Neurology, 1.2% from Internal Medicine, 1% from Cardiology, 0.6% from Rheumatology). Of note, our data evidenced isolated reactivity of anti-DFS70 autoantibodies in males group, while 51% of females showed concomitant disease-marker autoantibodies.

**Conclusions:** We found a prevalence of anti-DFS70 antibodies in adult sera from routine ANA cohort of 1.7%. The serological profile of DFS70-positive females required further investigations in order to define the presence of serum autoantibodies. Anti-DFS70 reactivity in male population may represent an exclusive biomarker predicting the absence of other autoantibodies.

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FRI0678

### VALIDITY OF THREE 0–10 VISUAL ANALOG SCALES (VAS) FOR QUANTITATIVE PHYSICIAN ASSESSMENT OF INFLAMMATION, DAMAGE, AND DISTRESS TO SUPPLEMENT A PHYSICIAN GLOBAL ASSESSMENT 0–10 VAS

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**Background:** Rheumatologists generally view their primary goal as control of inflammation in order to prevent long-term damage, and quantitative assessment involves measures of inflammatory activity (lab tests, joint counts, and indices). Although structural damage and patient distress (fibromyalgia, depression, etc.) are widely recognized, these problems generally are described narratively, and not assessed quantitatively. Recent advances in control of inflammation, as well as increased degenerative diseases in an aging population and recognition of a high prevalence of fibromyalgia, may have shifted rheumatologists' patient mix more prominently toward damage and distress vs inflammation.

**Objectives:** To analyze physician global assessment (DOCGL) on a 0–10 visual analog scales (VAS), and 3 additional 0–10 VAS for inflammation, damage, and distress, as well as estimates of the proportion of each to explain DOCGL.

**Methods:** Rheumatologists at one academic site complete a 0–10 DOCGL VAS, 3 further 0–10 VAS to assess inflammation (reversible disease) (DOCINF), joint and other organ damage (irreversible disease) (DOC DAM), and patient distress (fibromyalgia, depression), etc. (DOCSTR), in routine care. The proportion of DOCGL attributed to inflammation, damage, and distress (total=100%) also is estimated. Mean values were analyzed in a cross-sectional study of 570 patients, and compared in subgroups with rheumatoid arthritis (RA), osteoarthritis (OA), or fibromyalgia (FM), using t tests and analysis of variance (ANOVA).

**Results:** Mean DOCGL VAS was 4.4/10 in all patients, 4.4 in 131 with OA, 4.6 in 98 with RA, and 5.2 in 89 with FM (table 1). Highest mean scores were seen for DOCINF in RA, DOC DAM in OA, and DOCSTR in FM (p<0.001), indicating face validity. Nonetheless, mean DOC DAM was higher than DOCINF in all groups, including RA, and mean estimates of the proportion of DOCGL attributed to damage was greater than to inflammation in all groups (table 1). Scores for DOCSTR were higher than for DOCINF in all groups other than RA.