AstraZeneca and QIAGEN developed an *in-vitro* diagnostic test for interferon-inducible gene expression (IFIGx). Efficacy of anifrolumab will be evaluated in patients with high and low IFNGS.

Objectives: We aimed to analytically validate the IFIGx kit for use in a pivotal clinical study and potentially to support future regulatory submission.

Methods: The IFIGx kit measures expression of four interferon-inducible genes (IF127, IF114, IF114L and RSAD2) compared with three housekeeping genes. Measurements were performed on mRNA extracted from whole blood from adults with SLE. A score was generated that identified patients as "IFNGS test-high" or "IFNGS test-low." Analytical validation involved six studies measuring lot interchangeability, linearity, repeatability, reproducibility, cross contamination, and system verification.

Results: Repeatability was 100%. Reproducibility was >96%. No cross contamination was observed. Results of all studies validated the IFIGx kit (table 1).

Abstract AB1212 – Table 1

Summary of Analytical Validation of Anifrolumab IFIGx Test

Study	Description	Results
Lot interchangeability	Verification that scores and assay Ct values were robust when different lots of kit components were used Acceptance criterion was <0.58 Ct	Lot interchangeability verified Largest observed change=0.16 Ct
Linearity	Verification, using linear and quadratic regression analyses, that mRNA input concentration (10 ng/μL) is in assay's linear range	Linearity verified Change in score over the concentration range on either side of 10 ng/μL=0.0043 Ct
Repeatability	Verification of Dx result repeatability when the same operator tested 60 random samples using the same kit lot and instrument	Repeatability verified Observed repeatability=100%
Reproducibility	Verification of Dx result reproducibility when multiple operators tested 48 random samples using multiple kit lots and instruments at different sites For verification, overall rate of correct calls must be ≥95%	Reproducibility verified Overall rate=99.7% After six samples with values close to the cut-off were added for further confirmation, overall rate=96.5%
Cross contamination	Investigation of inter- and intra-run cross contamination	No cross contamination No cross contamination found in reverse transcription or PCR steps
System verification	Verification of functionality and utility of the IFIGx software and IFIGx assay package	System verification confirmed Software flags produced as expected

Ct, cycle threshold (PCR cycle at which fluorescence rises above background level); Dx, diagnostic; IFIGx, interferon-inducible gene expression; PCR, polymerase chain reaction; mRNA, messenger ribonucleic acid.

Conclusions: The IFIGx kit was shown to be a robust, reproducible diagnostic test for IFNGS. The IFIGx kit has demonstrated value in prior anifrolumab studies,¹ and will be used both for patient stratification in Phase III studies and to support anifrolumab regulatory filings.

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Disclosure of Interest: P. Brohawn Employee of: MedImmune LLC, B. Higgs Employee of: MedImmune LLC, S. Patel Employee of: AstraZeneca, A. Moody Employee of: QIAGEN Manchester Ltd, P. Cooper Employee of: QIAGEN Manchester Ltd, K. Ranade Employee of: MedImmune LLC

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AB1213 ULTRASONOGRAPHIC EVALUATION OF THE HIP JOINTS IN PATIENTS WITH AXIAL SPONDYLOARTHRITIS AND PSORIATIC ARTHRITIS: ASSOCIATED WITH CLINICAL AND LABORATORY MARKERS, IMAGING AND FUNCTIONAL OUTCOMES

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Background: The hip joints are frequently involved in spondyloarthritis (SpA). Should ultrasonography (US) be additionally used for clinical assessment of disease in patients (pts) with SpA.

Objectives: to detect by US synovitis of the hip joints and to analyse the correlation between US finding and magnetic resonance imaging (MRI) and/or X-ray sacroiliitis, clinical and laboratory markers and functional status in pts with axial SpA (axSpA) and psoriatic arthritis (PsA).

Methods: 13 pts (7M/6F) with definite axSpA (7 with ankylosing spondylitis (AS) and 6 with non-radiographic nrSpA:ASAS) and 7 pts (4M/3F) with PsA (CASPAR) of similar age [median (IQR), 44^{35–55} vs 42^{34–56} years] and disease duration [7 (1–10) vs 9^{7–10} years] were enrolled. US examination (Mindray DC-N6, C5–2 MHz probe) included bilateral of the hip joints according to the EULAR US Scanning App (www.eular.org; <http://ultrasound.eular.org>). MRI of sacroiliac joints (SIJ) was performed on Signa HDxT GE, 1.5 T. The bone marrow oedema on MRI (STIR) considered as active MRI sacroiliitis (MRI-SI).¹ X-ray of SIJs (modified New York criteria), functional status (BASFI), disease activity indices (ASDAS-CRP, DAPSA), laboratory tests (CRP, ESR, HLA-B27) were assessed.

Results: History of hip involvement was present in 7/20 (35%) pts who had ≥1 tender hip joint. 9/20 pts (45%) had US – synovitis of the hip joints. All pts were divided into two groups: g1 (n=9) – US synovitis "+" (at least one hip joint), g2 (n=11) – US – synovitis "–". Pts from g1 had higher CRP and BASFI compared to g2 (table 1). Elevated CRP ≥25 mg/L and ESR ≥30 mm/h, as well as MRI- and X-ray -SI were detected more often in g1pts than g2. But other parameters did not differ between the groups (table 1). US – synovitis of the hip joints was positively correlated with CRP (r=0.489, p<0.05), MRI-SI (r=0.688, p<0.05), X-ray-SI (r=0.634, p<0.05) and BASFI (r=0.541, p<0.05).

Abstract AB1213 – Table 1. Association between the US- synovitis of the hip joints and clinical and laboratory markers, imaging and functional outcomes

Parameters	US-synovitis "+" (n=9)	US-synovitis "–" (n=11)	P*
Age, years	44 (26–49)	46 (40–57)	.294
Duration since diagnosis, years	5 (1–10)	9 (7–10)	.551
AS/nrSpA/PsA	4 (57/3 (50)/2 (28.5))	3 (39/3 (50)/5 (71))	.411
Male sex	6 (67)	5 (45)	.456
HLA-B27	6 (67)	5 (45)	.456
CRP, mg/l	38 (6.7–51)	7.7 (3–19.2)	.031
Elevated CRP≥25	6 (67)	1 (9)	.031
ESR, mm/h	30 (16–39)	11 (6–25)	.080
Elevated ESR≥30	5 (55.5)	1 (9)	.027
ASDAS-CRP	3.4 (2.1–4.5)	2.7 (1.7–4.2)	.294
DAPSA	33 (19.6–46.4)	12.4 (12.3–12.4)	.190
BASFI (0–10)	5 (4–6)	3 (1.7–4)	.015
BASFI>4	6 (67)	2 (18)	.030
MRI-SI	9 (100)	5 (45)	<0.001
X-ray SI	9 (100)	5 (45)	<0.001

Numbers are medians (IQR) and n (%); * Mann-Whitney U-test.

Conclusions: US – synovitis of the hip joints was associated with CRP, MRI- and X-ray- SI and severe functional disability in SpA pts. US evaluation of the hip joints may be used for identifying SpA pts with high risk of the disease progression at an early stage.

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Disclosure of Interest: None declared

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AB1214 BONE MINERAL DENSITY AND T-SCORE EVALUATION IN A GROUP OF PATIENTS WITH RHEUMATOID ARTHRITIS USING A NEW ULTRASOUND METHOD: ECHOS – GENODYNAMIC - A PILOT STUDY –

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Background: There is a great need of a screening programme for osteoporosis in the general population and even more amongst the rheumatologic patients, with additional risk factors. Although DXA is the gold standard for diagnosing osteoporosis, it is not appropriate for screening, because of its' limitations regarding ionising radiation, but also the massive machine, that needs dedicated spaces and specialised operators, all in all, involving high costs.

Objectives: To apply a new method that integrates ultrasonography with radiofrequency signals from an echographic scan, in order to evaluate the bone mineral

density (BMD) and T-scores in patients with rheumatoid arthritis (RA), compared to a control group.

Methods: We enrolled 150 menopausal women, 75 diagnosed with RA and 75 age matched controls. The controls were selected considering the lack of both an inflammatory disease and history of corticotherapy.

All patients in the study group were under monotherapy with a conventional synthetic DMARD and they are or have been under corticotherapy during the evolution of RA.

The BMD and T score were evaluated using a quantitative ultrasound Echolight machine. There were two evaluators for both lots, on order to minimise the inter-observer variability.

Results:

Abstract AB1214 – Table 1

	Study group	Control group
Age distribution (years)	63,24 ⁴⁹ – 85	64,19 ⁴¹ – 85
Menopause age (years)	46,9 (34–60)	45,78 ³⁰ – 55
BMI (kg/m ²)	25.97 (15.63–34.86)	26.83 (18.36–33.67)
Period since dg of RA (years)	7.26 (5–12.5)	–

13% of the patients in the study group were under corticotherapy at the moment they were recruited in the study and 87% were treated with cortisone before, at some point during the evolution of RA. The average dose followed for more than 2 weeks was 8.8 (5–15) mg prednisone/day. The average corticotherapy period of 2.6 (0.5–14) months.

For the lumbar vertebrae (L1–L4), the average T score in the study group was –1.81, while the control group had a T score of –1.11. For the femoral neck, the average T score for both hips was –1.73 for the study group and –1.04 for the controls.

The spine average BMD was 0.92 g/cm² in the study group, compared to 1.16 g/cm² in the control group. For the femoral neck, the study group average BMD was 0.72 g/cm², while in the control group it was 0.94 g/cm².

Conclusions: The differences between the two groups were significant, but still in the osteopenia interval. The significance of these results translates into an increased fracture risk and a longer treatment duration in the study group.

At this point, this is a preliminary study, but we plan to continue it by comparing these results to DXA results for the same patients, in order to evaluate the cost-effective superiority of this portable, radiation-free technique, in a screening programme.

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AB1215

MINIMAL INVASIVE ULTRASOUND-GUIDED PAROTID GLAND BIOPSY IN CADAVERS DONE BY RHEUMATOLOGISTS

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Background: In daily practice, surgical biopsy of minor salivary glands is routinely performed for the diagnosis of Sjögren's syndrome. The classification criteria for Sjögren's syndrome imply specific positive labial salivary gland biopsy findings. Surgical biopsies of the minor labial glands may result in up to 6% of patients in various complications, e.g. numbness of the lower lip. On the other hand, adverse events following core needle biopsies of the parotid gland in non-rheumatological settings were reported as very rare. Even so parotid gland biopsies require a more demanding surgical expertise mainly to protect the facial nerve.

Objectives: The objective of this study was to assess the feasibility and to determine the presence of parotid gland tissue in minimally invasive ultrasound-guided

parotid gland biopsies in cadavers performed by rheumatologists using histology as a gold standard.

Methods: Two senior rheumatologists obtained under direct ultrasound visualisation in in-plane technique biopsies of 8 parotid glands from 4 different cadavers using a core biopsy needle (core biopsy needle 18G). One biopsy per gland was taken and was subsequently stored. The direction of the biopptic access is shown in Figure 1. The specimen underwent histological examination by an experienced pathologist.

Results: All histological exams showed typical parotid gland tissue. Notably, no facial nerve tissue or major vessels could be detected in the biopsy material.

Abstract AB1215 – Figure 1

Conclusions: In this cadaveric feasibility study, we demonstrated that minimally invasive ultrasound guided parotid core biopsy is a highly precise and easy method to obtain salivary gland tissue.

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AB1216

QUANTITATIVE EVALUATION OF THERAPEUTIC CHANGES IN DIGITAL PSORIATIC ARTHRITIS WITH CONTRAST ENHANCED DUAL ENERGY COMPUTED TOMOGRAPHY IODINE MAP

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Background: Dual Energy Computed Tomography (DECT) iodine map is highly sensitive in depicting the inflammatory changes of psoriatic arthritis (PsA). A modified PsA Magnetic Resonance Imaging Scoring System (mPsAMRIS) was developed to assess the severity of PsA on DECT iodine map^{1,2,3}. DECT iodine map also enables the calculation of iodine uptake in the lesion, which provides a more direct measure of disease activity⁴. However, the usefulness of DECT in evaluating the therapeutic effect of PsA by using iodine quantification, is still undetermined.

Objectives: To assess the validity of DECT iodine map in evaluating the therapeutic effect of PsA by iodine quantification.

Methods: The study included symptomatic PsA patients who underwent two consecutive contrast-enhanced DECT of hand or foot, prior and post medical intervention. All images were independently evaluated by two radiologists. Each symptomatic joint and matched non-symptomatic control joint were scored with mPsAMRIS. To measure the iodine uptake, the region of interest was selected at the level where the joint was most affected. The treatment effect of mPsAMRIS and iodine uptake was calculated by subtracting the results of the matched non-symptomatic joints.

Results: The demographics and clinical characteristics of enrolled patients are shown below.

Abstract AB1216 – Table 1

Demographic and patient Characteristics			
Characteristic	All patients	Men	Women
Number of patients	26	17	9
Mean age (yr)	50.6 (22–89)	54.2 (25–89)	45.2 (22–68)
Mean psoriasis duration (yr)	13.1 (0–41)	12.3 (0.5–35)	14.1 (0–41)
Mean current joint symptom duration (mo)	26.9 (1–192)	40.3 (1–192)	4.5 (1–120)
Fulfilled CASPAR criteria	26	17	9
Mean interval between two DECTs (mo)	7.0 (4–12)	7 (4–12)	6.4 (4–11)