session: (54–63 & 67–74; $p < 0.03$). Qualitative analysis mapped to previous themes will be summarised at the meeting.

Conclusions: It is feasible and effective to see new patients in a group setting with an experienced team. New patients group clinics have a powerful effect in empowering patients and may become an important option for hard to manage patients especially where resources are limited.

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FRI0639 THE IMPACT OF DISEASE ACTIVITY AND PAIN LEVEL ON PRODUCTIVITY IN RHEUMATOID ARTHRITIS (RA) PATIENTS

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Background: Rheumatoid arthritis (RA) is a disabling and progressive chronic autoimmune disease with associated burden in terms of work disability.

Objectives: To investigate the impact that RA associated pain and disease activity have on the level of work impairment patients experience, using data from the Burden of Rheumatoid Arthritis across Europe: a Socioeconomic Survey (BRASS).

Methods: Data were extracted from BRASS, a societal perspective observational RA dataset across 10 European countries (EU5, Denmark, Sweden, Hungary, Poland and Romania). 476 RA specialising clinicians provided information on 4,079 adult patients; of these, 2,087 patients completed corresponding questionnaires about the burden of RA. 646 patients were included in the analysis, having completed a patient questionnaire and with the physician having provided a DAS28-CRP score.

Descriptive analysis was used to explore the association between pain level, disease activity and productivity impairment due to RA. Summary measures were derived from BRASS data in which the Work Productivity and Activity Impairment Questionnaire was used to quantify impairment caused by the patient's RA, taking into account not only the proportion of time the patient is absent, but also the impact on their ability to perform their job. The relationship between disease severity (as measured by DAS28-CRP score), pain level (measured across 4 categories from 'no pain', 'mild', 'moderate' to 'severe pain') and overall work impairment was further explored using a generalised linear model where pain level and severity were modelled as explanatory variables against the overall work impairment outcome, while adjusting for covariates including age, gender and BMI.

Results: Of the 646 included in the analysis, average age was 54.6(14.1) years; mean (standard deviation), average DAS28-CRP score was 3.1(1.2), and average disease duration was 7(10) years; median (interquartile range). Descriptive analysis indicated that with greater levels of pain and/or disease activity, patients suffered increased levels of both work and activity impairment. The average marginal effect of covariates was calculated from regression outputs. Both pain level and DAS28-CRP score independently had a statistically significant association with work impairment; a unit increase in DAS28 score meant an increase in work impairment of 4.7% ($p=0.011$), whereas existence of 'mild', 'moderate' or 'severe pain' versus 'no pain' increased impairment by 33.3%, 43.4% and 45.0% respectively ($p < 0.05$), with confounders age, gender, BMI and either DAS28-CRP or pain level held constant.

Conclusions: Results from this large, multinational survey in Europe show that subjective domains of the disease, such as pain, could be as important as objective measures of RA activity in affecting a patient's ability to work; analysis suggested both pain and severity independently have a significant impact on work and activity impairment due to RA.

Disclosure of Interest: J. Galloway Consultant for: Receiving honorarium for speaking from Pfizer, UCB, Celgene and BMS, J.-P. Capron Employee of: Eli Lilly & Company, F. De Leonardi Shareholder of: Eli Lilly & Company, Employee of: Eli Lilly & Company, W. Fakhouri Employee of: Eli Lilly & Company, T. Burke: None declared

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FRIDAY, 15 JUNE 2018

Validation of outcome measures and biomarkers

FRI0640 AUTOANTIBODIES TO TWO NOVEL PEPTIDES IN SERONEGATIVE AND EARLY RHEUMATOID ARTHRITIS IN THREE LARGE INDEPENDENT COHORTS

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Background: Despite recent progress in biomarker discovery for RA diagnostics, still over one third of RA patients are seronegative for RF and ACPA, a number which is even higher in early disease. In both the University of Hasselt (UH) cohort ($n=292$) and Leiden Early Arthritis Clinic (EAC) cohort ($n=600$), 38% of RA patients were seronegative for RF and ACPA. Testing for novel autoantibodies to UH peptides UH-RA.1 and UH-RA.21, reduced the serological gap from 38% to 29% in the UH cohort ($P=0.03$) and from 38% to 32% in the EAC cohort ($P=0.01$), with associated specificities in rheumatic controls ranging from 88–96%¹.

Objectives: Our aim is to validate the reactivities of autoantibodies against UH-RA.1 and UH-RA.21 peptides in early and seronegative RA patients from the CareRA cohort.

Methods: Peptide enzyme-linked immunosorbent assays have been developed to screen for the presence of antibodies to UH-RA peptides. Cut-off for seropositivity was defined by $2 \times$ SD above the mean antibody level of the healthy control group¹. Antibody reactivity to UH-RA.1 and UH-RA.21 was evaluated in baseline samples, collected before the start of treatment, of 223 early RA patients from the CareRA cohort.

Results: Antibodies to UH-RA.1 and UH-RA.21 were found in respectively 5% and 21% of the baseline samples from the CareRA cohort. These antibodies were found in similar levels in both RF/ACPA seropositive and seronegative patients. In the CareRA cohort, 24% of patients were seronegative for RF and ACPA and combining the presence of autoantibodies to UH-RA.1 and UH-RA.21 with RF/ACPA serology, reduced the seronegative population from 24% to 18% ($P=0.13$).

Conclusions: Screening for antibodies against novel UH peptides UH-RA.1 and UH-RA.21 has now been performed in three large independent cohorts. This study validates the presence of antibody reactivity to these UH-RA peptides in seronegative and early RA. This might reinforce current diagnostics and improve early diagnosis and intervention in RA.

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FRI0641 DETECTION OF CHANGES IN SLE DISEASE ACTIVITY IS HIGHLY IMPROVED WITH SLE-DAS AS COMPARED TO SLEDAI: DERIVATION AND PRELIMINARY VALIDATION OF THE SLE DISEASE ACTIVITY SCORE (SLE-DAS)

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Background: SLEDAI is a widely used instrument to measure disease activity of systemic lupus erythematosus (SLE). However, it lacks sensitivity to discriminate improvement/worsening as it only scores items categorically and does not include several relevant lupus features, such as hemolytic anemia.

Objectives: To derive and validate a SLE Disease Activity Score (SLE-DAS) with improved sensitivity to change, while maintaining the high specificity and simplicity of use of the SLEDAI.

Methods: 324 patients fulfilling ACR'97 and/or SLICC'12 classification criteria for SLE and regularly followed at a tertiary care lupus clinic from January 2014 to December 2017 were included. At each outpatient visit, clinical and laboratory data were collected and disease activity (last 30 days) was scored with Physician Global Assessment (PGA) (0–3 scale) and SLEDAI-2K. To derive the SLE-DAS

we analyzed data from the study visit with higher disease activity from each patient, applying multivariate linear regression analysis, with PGA as dependent variable/gold-standard. Independent variables tested in the models included items from SLEDAI-2K and continuous variables for swollen joint count, proteinuria, platelet and white blood cells counts. Some features absent from SLEDAI, such as hemolytic anemia, gastrointestinal and cardiopulmonary involvement were added to the model.

To assess correlation validity we performed a Spearman's correlation between the SLE-DAS, PGA and SLEDAI-2K at last follow-up visit. We tested performance of SLEDAI-2K (change ≥ 4) and SLE-DAS to discriminate a clinically meaningful worsening and improvement in SLE disease activity (change in PGA ≥ 0.3) using Receiver Operating Characteristic (ROC) curve analysis. We determined the best cut-offs values of SLE-DAS to detect changes in PGA ≥ 0.3 and calculated the sensitivity, specificity, positive and negative predictive values (PPV, NPV). Statistical significance was set at 0.05.

Results: The final SLE-DAS model included 17 items. The SLE-DAS score at last follow-up visit presented high correlation with PGA ($\rho=0.975$, $p<0.0005$) and SLEDAI-2K ($\rho=0.94$, $p<0.0005$). For improvement in PGA ≥ 0.3 , in ROC analysis a change in SLE-DAS presented a much higher performance [area under curve (AUC)=0.927 (95% CI=0.885–0.969, $p<0.0005$)] than SLEDAI-2K [AUC=0.787 (95% CI=0.718–0.857), $p<0.0005$] (figure 1). For worsening of PGA ≥ 0.3 , change in SLE-DAS and SLEDAI-2K presented an AUC of 0.994 (95% CI=0.988–1.000, $p<0.0005$) and 0.914 (95% CI=0.870–0.959, $p<0.0005$), respectively (figure 1). The optimal discriminative cut-off for either a PGA increase or reduction was change in SLE-DAS ≥ 1.72 (table 1).

Table 1 Performance of SLE-DAS and SLEDAI-2K to detect change in SLE disease activity

	Δ SLE-DAS ≥ 1.72				Δ SLEDAI-2K ≥ 4			
	Sens	Spec	PPV	NPV	Sens	Spec	PPV	NPV
Improvement	82.1	96.9	87.3	95.4	44.8	96.5	76.9	87.0
PGA ≥ 0.3								
Worsening PGA ≥ 0.3	93.1	97.7	90.0	98.5	46.6	99.6	96.4	89.5

Sens: Sensitivity(%); Spec: Specificity(%); PPV: Positive predictive value(%); NPV: Non predictive value(%).

Figure 1 Receiver operating curve (ROC) comparing the performance of SLE-DAS and SLEDAI-2K to detect a clinical meaningful improvement (A) and worsening (B) in SLE disease activity.

Conclusions: The SLE-DAS presents good construct validity and much higher discriminative power to detect changes in SLE disease activity as compared to SLEDAI-2K. External validation in another SLE cohort is underway.

Disclosure of Interest: None declared

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FRI0642 SEPTIC ARTHRITIS SCREENING WITH A FAST DIAGNOSTIC TOOL USING MID INFRARED SPECTROSCOPY: A MULTI-CENTRIC STUDY

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Background: Septic arthritis diagnostic is an emergency which implies a treatment with antibiotics and hospitalization. The diagnosis is based on the cyto-bacteriological examination of the synovial fluid (SF), but direct bacteriological examination is insensitive and the result of the culture is obtained only after several days. Therefore, there is still a need for a rapid, simple and reliable method for

the positive diagnosis of septic arthritis. Such method must allow avoiding both unrecognized septic arthritis leading to major functional consequences, and over-diagnosis that will induce unnecessary expensive hospitalization and unjustified treatment with consequences in term of health and social costs.

Mid-infrared (MIR) spectroscopy, that gives a metabolic profiling of biological samples, has been proposed for early and fast diagnosis.

Objectives: The objective of this study was to confirm ⁽¹⁾ the interest of mid-infrared (MIR) spectroscopy to discriminate synovial fluid samples from patients with septic arthritis from other causes of joint effusion.

Methods: Synovial fluids from patients referred for suspected arthropathies were prospectively collected in six hospitals in western France and stored at -80°C. The infrared absorption spectrum was acquired for each of the frozen samples using a chalcogenide fibre sensor. The most informative spectral variables (allowing to discriminate between septic arthritis and non-septic arthritis with reference to cytobiological examination) were selected and then used to develop an algorithm. Non-frozen synovial fluids were also analysed at Rennes University Hospital, the pilot centre, to validate the algorithm.

Results: The cohort consists of synovial fluid samples from patients exhibiting various etiologies. These samples (n=402), by using SF bacteriological analysis and culture and 16S PCR analysis were classified as septic arthritis (n=30) or non septic arthritis (n=372).

On the frozen samples the performances of the algorithm show a sensitivity of 97%, a specificity of 71%, a **VPN of 99%** and a VPP of 21%, the area under the ROC curve (AUROC) was 0.91.

Conclusions: This study confirms the interest of optical fibre infrared spectroscopy for the discrimination between septic and non septic synovial fluids. The high negative predictive value and the very short time (about ten minutes) required to obtain the result makes it possible to quickly rule out an infection diagnosis, which could make it possible to avoid unnecessary hospitalization and antibiotic therapy.

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Disclosure of Interest: J.-D. ALBERT: None declared, M. Le Corvec Employee of: DIAFIR, A. MARTIN: None declared, X. GUENNOC: None declared, C. DAVID: None declared, S. HOANG: None declared, C. GUEDES: None declared, M. FERREYRA: None declared, E. HOPPE: None declared, B. LEGOFF: None declared, S. JOUSSE-JOULIN: None declared, H. TARIEL Shareholder of: DIAFIR, O. SIRE Consultant for: DIAFIR, A. JOLIVET-GOUGEON: None declared, P. GUGGENBUHL: None declared, O. LOREAL Shareholder of: DIAFIR

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FRI0643 AUTOANTIBODY STATUS IS NOT ASSOCIATED WITH EARLY TREATMENT RESPONSE TO FIRST-LINE METHOTREXATE IN PATIENTS WITH EARLY RHEUMATOID ARTHRITIS

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Background: In rheumatoid arthritis (RA), the relationship between autoantibody status and treatment response to methotrexate remains unclear. As methotrexate is the most widely used anti-rheumatic drug in clinical practice, it would be important to know whether the presence of autoantibodies is associated with better treatment response, since patients may benefit from treatment tailored to "autoantibody status".

Objectives: We investigated the relationship between autoantibody status and remission in newly diagnosed RA-patients treated with first-line methotrexate.

Methods: RA-patients initially treated with methotrexate were selected from an international observational database (METEOR). Patients were stratified into autoantibody-positive (rheumatoid factor (RF)- and/or anti-citrullinated-protein antibodies (ACPA)-positive) or -negative (RF- and ACPA- negative). The effect of autoantibody status on the chance of achieving remission within 3 to 6 months was analysed using Cox-proportional hazards regression.

Results: Data from 1826 RA-patients were available for analysis. DAS remission was achieved in 17% (318/1,826). This was similar in autoantibody-positive (17% (282/1629)) and -negative patients (18% (36/197)). Hence, autoantibody positivity was not associated with remission (HR0.89, 95%CI 0.57;1.38). Similar findings were found when stratified for methotrexate monotherapy (HR0.75, 95%CI 0.41;1.37) or combination treatment (HR0.76, 95%CI 0.37;1.54). Good physical

function (HAQ<0.5) was achieved in 33% (530/1590) of all patients. Autoantibody-positivity was also not associated with HAQ<0.5 (HR1.05, 95%CI 0.71;1.57).

Table 1 Patient characteristics at baseline

Characteristic	All RA-patients n=1,826		Autoantibody-positive n=1,629		Autoantibody-negative n=197	
	Values available	Summary statistics	Values available	Summary statistics	Values available	Summary statistics
ACPA (positivity), n (%)	1,821	889 (75)	924	889 (90)	197	0 (0)
RF (positivity), n (%)	1,810	1,554 (85)	1,613	1,554 (96)	197	0 (0)
Gender (female), n (%)	1,814	1,429 (79)	1,620	1,288 (80)	194	141 (73)
Age at diagnosis (years), mean ±SD	1,815	48±13	1,619	47±13	197	54±16
Symptom duration (months), median (IQR)	1,826	15 (6-36)	1,629	18 (7-36)	197	7 (3-17)
Visit count, mean ±SD	4,265	3.14±1.05	3,782	3.13±1.02	483	3.27±1.24
Follow-up duration (months), mean ±SD	1,826	4.2±1.2	1,629	4.2±1.2	197	4.2±1.1
Cigarette smoking, n (%)	1,602		1,461		141	
Never		1,353 (85)		1,250 (86)		103 (73)
Current		158 (10)		140 (10)		18 (13)
Past		91 (6)		71 (5)		20 (14)
ESR (mm/hr), median (IQR)	1,588	51 (29-85)	1,413	55 (31-85)	175	30 (15-48)
CRP (mg/L), median (IQR)	1,498	23 (9-49)	1,324	24 (11-52)	154	10 (1-24)
VAS, median (IQR)	1,357	50 (50-75)	1,212	50 (50-75)	145	50 (50-75)
SIC in all joints, median (IQR)	1,664	5 (2-10)	1,492	5 (2-10)	172	6 (3-11)
RAI, median (IQR)	1,661	9 (5-16)	1,489	10 (5-16)	172	6 (4-9.5)
DAS, mean ±SD	1,078	3.8±1.1	979	3.9±1.0	117	3.4±1.1
HAQ, median (IQR)	1,505	1.0 (0.6-1.6)	1,384	1.0 (0.6-1.6)	121	1.1 (0.5-1.6)
First-line treatment strategy:						
MTX monotherapy, n (%)	1,826	653 (36)	1,629	549 (34)	197	104 (53)
MTX & prednisone, n (%)	1,826	806 (44)	1,629	728 (45)	197	78 (40)
MTX & synthetic DMARD, n (%)	1,826	351 (19)	1,629	338 (21)	197	13 (7)
MTX & biological DMARD, n (%)	1,826	16 (1)	1,629	14 (1)	197	2 (1)

ESR data are mean and SD or median and interquartile range (IQR); 75th percentile; ACPA, anti-citrullinated protein antibody; RF, rheumatoid factor; ESR, erythrocyte sedimentation rate; CRP, C-reactive protein; VAS, visual analogue scale general health patient; SIC, swollen joint count on a 44-joint count; RAI, Ritchie articular index on a 53-joint count; DAS, disease activity score (DAS) on a 44-joint count; HAQ, health assessment questionnaire; DMARD, disease-modifying anti-rheumatic drug.

Conclusions: In conclusion, we found that autoantibody status was not associated with early remission in newly diagnosed RA-patients receiving methotrexate in real-world clinical practice. These results do not support the hypothesis that treatment should be tailored to "autoantibody status" when it comes to initiating methotrexate therapy as first-line anti-rheumatic treatment. Rather, our results indicate that that methotrexate is effective as primary anchor drug regardless of autoantibody status.

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FRI0644

THE USE OF MRI-DETECTED SYNOVITIS TO DETERMINE THE NUMBER OF INVOLVED JOINTS FOR THE 2010 ACR/EULAR CLASSIFICATION CRITERIA FOR RHEUMATOID ARTHRITIS – IS IT OF ADDITIONAL BENEFIT?

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Background: The 2010 ACR/EULAR classification criteria have been developed, as early classification of Rheumatoid Arthritis (RA) is important. The 2010-criteria states that imaging can be used to determine the number of joints with synovitis. This seems reasonable as previous studies on Magnetic Resonance Imaging (MRI) in early arthritis patients have shown that synovitis is present in a substantial number of joints that were neither swollen nor tender at clinical examination. Although the development of the 2010-criteria was primarily data-driven, the suggestion to also use advanced imaging modalities to detect synovitis was based on expert opinion. Scientific data supporting the use of MRI is lacking.

Objectives: To assess the value of MRI-detected synovitis to determine the number of involved joints on the performance of the 2010-ACR/EULAR classification criteria for RA.

Methods: 277 consecutive patients with a clinical diagnosis of RA or undifferentiated arthritis (UA) were studied. They underwent contrast enhanced 1.5T MRI of MCP-, wrist- and MTP-joints at baseline. Two outcomes were studied after 1 year follow-up: disease modifying anti-rheumatic drugs (DMARD)-initiation and fulfilling the 1987-criteria. Test characteristics were calculated when the number of involved joints was determined with and without MRI-detected synovitis.

Results: At baseline, 143 of 277 patients did not fulfil the 2010-criteria when the number of involved joints was determined by clinical evaluation of swelling and tenderness. When MRI-detected synovitis was also considered 69 patients had increased joint counts. Of these, 36 patients received more points for the item 'number of involved joints' and 14 reached ≥6 points and now fulfilled the 2010-criteria for RA. Thus, 10% of patients that were formally classified as UA were additionally classified as having RA.

Without considering MRI-detected synovitis, the sensitivity of the 2010-criteria was 62% and the specificity 90%, for DMARD initiation as outcome. With the addition of MRI-detected synovitis, the sensitivity increased to 67% and the specificity decreased to 84%. The AUC changed from 0.76 to 0.75. The net proportion of correctly reclassified patients was -2.4%. Of the additionally classified patients, 64% (9/14) were started on DMARDs and were considered true positives, whereas 36% (5/14) were not treated with DMARDs and developed alternative clinical diagnoses during the first year.

Results for the outcome 1987-criteria fulfilment after 1-year were similar. The sensitivity changed from 79% to 81% and the specificity from 78% to 71% the proportion or correctly reclassified patients was -5.1%.

Conclusions: To our knowledge, this study is the first providing evidence on the value of MRI-detected synovitis in addition to tender and swollen joints for the classification of RA. We did not find an increased accuracy of the 2010 criteria when incorporating MRI-detected synovitis. Further research on this subject in other longitudinal cohorts is needed, but at present there is no scientific proof that MRI-detected synovitis is of additional benefit for classifying RA.

Disclosure of Interest: None declared

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FRI0645

ANTI-DRUG ANTIBODIES TO CERTOLIZUMAB PEGOL ARE ASSOCIATED WITH LOW DRUG LEVELS AND REDUCED CLINICAL RESPONSE AT 3 MONTHS IN PATIENTS WITH INFLAMMATORY JOINT DISEASES. DATA FROM THE NOR-DMARD STUDY.

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Background: Anti-drug antibodies (ADAb) to biological drugs predispose patients to low drug levels and lack of treatment response. For certolizumab pegol (CP) knowledge about the frequency and clinical relevance of ADAb is limited in patients with inflammatory joint diseases (IJD).

Objectives: To assess the frequency and clinical relevance of early ADAb development in patients with inflammatory joint diseases treated with CP.

Methods: Patients from the NOR-DMARD study (n=310) with a clinical diagnosis of rheumatoid arthritis (RA, n=91), psoriatic arthritis (PsA, n=61), axial spondyloarthritis (axSpA, n=116) and other IJD (42) starting treatment with CP, who had available biobank sample at 3 months follow-up, were included. Serum samples are non-through samples collected at 3 months. Drug concentrations were analysed using an in-house immunofluorometric assay automated on the AutoDEL-FIA immunoassay platform. ADAb was detected by a principal assay measuring neutralising ADAb and two confirmational tests (antigen-bridging test and a 3-step immunofluorometric assay). Patients with RA, PsA and axSpA were included in response analyses. Treatment response was defined by EULAR good/moderate response in RA, DAS28 improvement ≥0.6 in PsA, and ASDAS clinically important improvement (CII) in axSpA.

Results: After 3 months of treatment, 19 of 310 (6.1%) patients were ADAb positive (5 RA, 4 PsA, 6 axSpA and 4 other IJD). ADAb positive patients had significantly lower CP levels than ADAb negative patients, median 1.0 (IQR 0.2–6.8) vs 34.4 (IQR 21.2–44.7) mg/L (P<0.001). Response data were available for 245 patients. Of these, only 1/11 (9%) ADAb-positive patients was classified as a responder, while 10/11 (91%) were non-responders. Among ADAb-negative patients with response data, 129/234 (55%) were responders, while 105/234 (45%) were non-responders.

Conclusions: ADAb against CP were detected in 6.1% of patients after 3 months of treatment and were associated with low drug levels and reduced treatment response. These results suggest that drug levels and ADAb may be important for monitoring efficacy of treatment with TNF inhibitors, but the clinical significance needs to be examined in randomised clinical strategy trials.

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FRI0646

SYNOVIAL TISSUE HISTOPATHOLOGY FINDINGS IN EARLY RA. IS IT USEFUL? ANALYSIS OF THE BELGIAN CAP48 COHORT.

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Background: The development of ultrasound-guided synovial biopsy will enable synovial tissue collection from small joints and will facilitate histopathological studies, thus improving the understanding of early rheumatoid arthritis (ERA). The CAP48 cohort is an original multicentre prospective observational study of early