Methods: A common data model for PsA was agreed upon by the EuroSpA Scientific Committee. Virtual meetings between the EuroSpA and registry data managers clarified data availability and structure. This was followed by upload of anonymized data through the secure Virtual Private Network pipelines to the EuroSpA server. Baseline characteristics and disease activity at baseline and after 6 months were investigated with non-parametric descriptive statistics. Kaplan-Meier estimation was used to investigate TNFi retention rates.

Results: By January 8th 2018, four of the 15 registries participating in EuroSpA had completed data upload to the EuroSpA database resulting in 3172 patients with PsA in a pooled dataset. Baseline characteristics of the participating registry populations at initiation of first TNFi are shown in table 1. Crude 12 month TNFi retention rates varied from 65%–80% for 1st TNFi and 57%–82% for 2nd TNFi (see figure 1). For the pooled dataset crude 12 months TNFi retention rates were 68% and 60% for the 1st and 2nd TNFi, respectively.

Abstract THU0317 – Table 1. Baseline demographic and disease characteristics of patients with PsA registered in four EuroSpA registries

	DANISH (Denmark)	BIOIC (Belgium)	TURK-BIO (Turkey)	ICERON (Croatia)				
	N=2379	N=375	N=93	N=239				
Age, years	48 (9-56)	49 (13-57)	45 (30-55)	50 (18-59)				
Male/female	1488 (46)	205 (17)	33 (35)	158 (44)				
cDAS28 (n°)	1456 (43)	228 (17)	29 (30)	173 (43)				
Disease duration, years	7 (1-13)	6 (2-12)	7 (2-16)	7 (1-16)				
Smoking status, current, n (%)	184 (7)	34 (9)	21 (24)	18 (5)				
First TNFi drug, n (%)								
• INF	415 (3)	37 (9)	26 (28)	163 (42)				
• ETA	355 (10)	73 (19)	22 (24)	11 (27)				
• ADA	174 (5)	189 (48)	44 (48)	71 (18)				
• CCR	178 (7)	12 (3)	0 (0)	1 (1)				
• GOL	122 (3)	49 (13)	2 (2)	42 (10)				
First TNFi start, yr								
• Before 2009	423 (12)	28 (7)	18 (19)	93 (23)				
• 2009-2011	648 (19)	181 (48)	24 (26)	48 (12)				
• 2012-2017	1609 (48)	226 (59)	51 (55)	108 (27)				
	Baseline	6 months	Baseline	6 months	Baseline	6 months	Baseline	6 months
DAS28-CRP	4.3 (3.4-5.3)	2.5 (1.3-4.1)	5.4 (2.3-8.1)	2.7 (1.2-5.9)	2.4 (1.2-5.1)	4.4 (3.1-5.8)	2.1 (1.6-3.3)	
CRP, mg/L	7.2 (3.9)	2.1 (1.6)	8.0 (3.9)	2.0 (1.7)	2.0 (1.7)	7.7 (3.9)	3.3 (1.8)	
VAS for physical pain	78 (18.8)	18 (14.6)	30 (32.8)	30 (32.8)	28 (30.8)	71 (25.8)	37 (24.4)	
VAS for joint pain	42 (10.7)	28 (13.5)	20 (21.9)	20 (21.9)	22 (24.0)	48 (22.9)	28 (14.7)	

Data are as observed, mean (SD) or percentage. cDAS28 = conventional DAS28 Modified ACR EULAR score. CRP = C-reactive protein. DAS28 = Disease Activity Score in 28 joints. VAS for Physical Pain = Visual Analogue Scale for physical pain.

Data are as observed, median (IQR) or percentage. cDAS28 = conventional synthetic disease activity index; ADA = Ankylosing Spondylitis Disease Activity Index; CCR = Crohn's Disease Activity Index; GOL = Golimumab; INF = Infliximab; ETA = Etanercept; ADA = Adalimumab; CCR = Certolizumab pegol; GOL = Golimumab; CRP = C-reactive protein; DAS28-CRP = Disease Activity Score in 28 joints; VAS for physical pain = Visual Analogue Scale physical pain global.

Conclusions: Preliminary analyses showed differences across European registries regarding baseline characteristics and crude retention rates in PsA patients initiating TNFi. These initial, preliminary analyses demonstrate that the creation of a large European database of PsA patients treated in routine care based on a common data model is feasible, offering important opportunities for future research.

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THU0318

TREATING PSORIATIC ARTHRITIS TO TARGET: COMORBIDITIES, NON-ADHERENCE AND FACTORS RELATED TO THE HEALTH SYSTEM PREVENT ESCALATION OF THERAPY IN REAL LIFE

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Background: Although the treat-to-target (T2T) strategy in psoriatic arthritis (PsA) clinical trials resulted in better outcomes in domains such as joints, skin, function and quality of life compared to standard care, in real life several factors affect such a strategy¹.

Objectives: To determine the prevalence of patients achieving minimal disease activity (MDA) in our PsA clinic and the reasons why therapy in patients not achieving MDA was not optimised.

Methods: An observational, retrospective cross-sectional study nested in a cohort study was conducted; medical records of patients attending PsA clinic in a public university hospital were reviewed. Demographic data, current treatment and components of the MDA score were collected. When patients were not in MDA but the treatment was not optimised, the reasons for the non-escalation of therapy were recorded.

Results: MDA score was available in 113 visits, corresponding to 69 patients. Mean age of patients was 57.4±10.6, 53.6% (n=37) were females and 40.6% (n=28) were treated with biological drugs. MDA was reached in 31.0% (n=35) of visits; 36.2% (n=25) of the patients achieved MDA in at least one visit during the 8 months follow-up. There was no statistical difference in the proportion of patients achieving MDA according to treatment prescribed (biological DMARDs versus synthetic conventional DMARDs) (p=0.979). Although MDA was not achieved in 69.0% (n=78) of visits, optimisation of therapy was done in only 42.3% (n=33) of those visits. The main reasons which prevented treatment escalation were: physician impression of clinical remission and MDA overestimated by comorbidities and chronic deformities (57.7%, n=26), non-adherence to previous prescription (17.8%, n=8), delay to receive drugs from health insurance (17.8%, n=8), adverse events (11.1%, n=5), patient low cognitive level (6.7%, n=3) and patient refusal to escalate therapy (4.4%, n=2). In visits with impression of remission by rheumatologist, the skin and the swollen joint components of the MDA score were achieved in more than 80% of this visits (80.8%, n=21).

Conclusions: Rheumatologists are reluctant to escalate therapy in PsA even if patients are not in MDA if "objective" components of the MDA score such as skin and swollen joint counts are reached. Comorbid conditions, patients non-adherence to therapy and factors related to the health system influence a tight control strategy in the real life clinical practice.

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THU0319

OVERALL SAFETY OF 7-WEEK SECUKINUMAB EXPOSURE DURING PREGNANCY IN WOMEN WITH PSORIATIC ARTHRITIS

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Background: Psoriatic arthritis (PsA) often affects women of reproductive age. Secukinumab (SEC), a monoclonal antibody against interleukin-17A is effective in contrasting the progression of articular and cutaneous manifestations of PsA but has not been extensively studied in pregnancy, despite 84 cases of accidental exposure reported with reassuring safety outcomes.

Objectives: To evaluate the maternal and fetal outcomes in women with PsA exposed to SEC during pregnancy.

Methods: During a 10 months observational period, we enrolled 6 patients, treated by SEC 150 mg subcutaneously every month after weekly induction. All of them stopped the treatment by the time pregnancy test turned positive. All women had previously been counselled about contraceptive methods adoption and the potential risk of becoming pregnant during SEC administration, signing an informed consent. We collected demographic and clinical data of both patients

and babies, with a peculiar focus on maternal-fetal safety issues. APGAR scores at 1 min (APGAR1) and 5 min (APGAR5) from delivery were recorded.

Results: We observed 6 pregnancies from 6 mothers (4 of European, 1 Asian and 1 Latin-American ethnicity). Patient mean age at conception was 336±131 months; disease duration, 62±27 months; pre-conceptional exposure, 46±9 weeks; the (estimated) post-conceptional exposure 7±2 weeks. No major gestational complications were reported. One mother consulted the Emergency Department for a syncopal episode, but after a routine evaluation and an observation of 6 hours, was discharged; her pregnancy was otherwise unremarkable. Four girls (mean weight: 3170±200 g) and 2 boys (mean weight: 3460±60) were born. Mean gestational age was 38±2 weeks; 3 vaginal deliveries (1 oxytocine-induced for scarce dilation) and 3 caesarean sections were observed. The APGAR scores were above 8, excepting for an APGAR1 of 6 (born with caesarean section), then turned on 10 at APGAR5. Results are summarised on table 1. DAPSA, for the whole population, was under 4 (remission) at conception, and remained stable after delivery.

Abstract THU0319 – Table 1

Observed pregnancies	6					
Gestational age (weeks+days)	38±2					
Sex	M (4)			F (2)		
Birth weight (g)	3460±60			3170±200		
APGAR						
1 minute	6	10	9	9	8	10
5 minute	10	10	10	10	10	10
Delivery modality						
Vaginal spontaneous		1		1		1
Vaginal induced					1	
Cesarean section	1		1			1
Complications	-	-	-	-	-	ED
Malformations	-	-	-	-	-	-
Growth restrictions (SGA, IUGR)	-	-	-	-	-	-
Maternal age at conception (months)	336±131					
PsA duration at conception (months)	62±27					
PsA activity at conception (DAPSA)	<4	<4	<4	<4	<4	<4
Pre-conceptional exposure (weeks)	46±9					
Post-conceptional exposure (weeks)	7±2					
PsA activity postpartum (DAPSA)	<4	<4	<4	<4	<4	<4

APGAR, Appearance-Pulse-Grin-Activity-Respiratory Score; SGA, Small for Gestational Age; IUGR, Intra-Uterine Growth Restriction; PsA, Psoriatic arthritis; DAPSA, Disease Activity in Psoriatic Arthritis; ED, Emergency Department (access).

Conclusions: The present study, despite the limited number of observations, represents the first report on pre-conceptional exposure to SEC. The available data, due to the lack of controlled studies, place the drug's use on FDA "B" category. Of note, SEC failed to cause teratogenicity, when administered throughout the whole pregnancy in a study conducted on primates (*Cynomolgus* monkeys). The limited knowledge on human beings suggests, nevertheless, not to administer SEC during pregnancy, unless a clear benefit overwhelm the potential risk. SEC, in conclusion, seems to have an acceptable safety profile, even when accidentally taken in the very first pregnancy phase. Reporting the cases of pregnancy exposures, as recommended by the ongoing Producer's policy, is the only way that would allow to confirm, or reject, this statement. A long-term follow-up of the mother and the offspring health, similarly, is needed.

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THU0320

A SHORT, EASILY READABLE, ONLY 3-ITEM TOOL – BRISTOL RHEUMATOID ARTHRITIS FATIGUE SCALE (BRAFF) – IS VALID IN PATIENTS WITH PSORIATIC ARTHRITIS

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Background: Fatigue in Psoriatic arthritis is very little studied. Recently, an instrument, the Functional Assessment of Chronic Illness Therapy (FACIT), has been validated in PsA, which is a relatively long, 13-item, instrument. An alternative instrument, the Bristol Rheumatoid Arthritis Fatigue Numerical Rating Scales (BRAFF-NRS), is an easily readable, much shorter, 3-item tool. The BRAFF-NRS

has been studied and validated in rheumatoid arthritis population; however, this has not been validated in patients with PsA.

Objectives: The purpose of this study was firstly to determine the internal consistency, test-retest reliability, criterion validity of the BRAFF-NRS in patients with PsA. Secondly, we also examined the potential clinical associations of worse fatigue in patients with established PsA.

Methods: Two independent cohorts fulfilling CASPAR criteria were enrolled.

STUDY PHASE 1: BRAFF-NRS SCALE VALIDATION COHORT (n=70)

A consecutive cohort of 70 PsA patients completed the 3-item BRAFF-NRS scale and 13 items of the FACIT-F scale, alongside laboratory testing and disease activity assessments. Moreover, all these patients completed BRAFF-NRS questionnaires twice, one day apart. Internal consistency was measured by Cronbach's alpha; test-retest reliability by the intra class correlation coefficient (ICC); and validity by the correlation of the BRAFF-NRS results with validated FACIT-F measures.

STUDY PHASE-2: IDENTIFYING THE POTENTIAL CLINICAL ASSOCIATIONS OF FATIGUE BY USING BRAFF-NRS (n=283)

Following informed consent, patients underwent a detailed skin and rheumatologic assessment including disease activity measures, and whether patient has achieved minimal disease activity (MDA). Moreover, we measured comorbidity using the Charlson Comorbidity Index (CCI). The factors predicting worse fatigue as measured by the BRAFF-NRS score were determined using univariate and multivariate linear regression analysis.

Results: **STUDY PHASE 1: BRAFF-NRS SCALE VALIDATION COHORT (n=70):** 67 patients had the complete assessments [mean age 52±9 years, 54% female, mean PsA duration of 5±3 years]. The internal consistency of the 3 items BRAFF-NRS questionnaire as measured by Cronbach's alpha was 0.92. Test-retest reliability as measured by the intraclass correlation coefficient between the first and repeat questionnaires was 0.98. The BRAFF-NRS scores were compared with the FACIT fatigue scores. There was an excellent correlation between the BRAFF-NRS and FACIT fatigue ($r=-0.83$ ($p<0.001$)).

STUDY PHASE-2: IDENTIFYING THE POTENTIAL CLINICAL ASSOCIATIONS OF FATIGUE BY USING BRAFF-NRS (n=283)

On multiple linear regression analysis, the model predicted the significant association of low education status ($p=0.03$), number of deformed joints ($p=0.01$), not achieving MDA ($p<0.001$), higher CCI scores and worse HAQ ($p<0.001$) with worse fatigue scores.

Conclusions: BRAFF-NRS provides a reliable, reproducible and valid instrument of measuring fatigue in PsA. Fatigue is associated with low education status, higher number of deformed joints and comorbidities, not achieving remission and worse functional index. This short assessment tool can be especially valuable in the context of a busy clinic, and also in large epidemiological studies when other core domains warrant assessment.

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THU0321

ACUTE PHASE MARKERS IN PSORIATIC ARTHRITIS IDENTIFY PATIENTS WITH A MORE SEVERE PHENOTYPE

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Background: CRP and ESR are the most commonly and probably the most studied inflammatory markers among patients with inflammatory arthritis. In contrast to rheumatoid arthritis, however, these markers are raised in less than 50% of people with psoriatic arthritis (PsA). Little is known about the long term significance of elevated inflammatory markers during the course of PsA disease.

Objectives: In a well characterised PsA cohort with a long term follow up, we examined the association of CRP and ESR over the disease course with demographics, clinical and radiographic features, patient reported outcome measures and the number of comorbid conditions.

Methods: A cohort of 283 PsA patients all meeting CASPAR criteria and attending rheumatology clinics were evaluated. All underwent detailed skin and rheumatologic assessments, along with cardiovascular risk factor evaluation. Moreover, we documented the presence/absence of comorbidities using the Charlson Comorbidity Index (CCI). All of these patients had CRP and ESR laboratory values assessed along with the other routine laboratory parameters during the disease course. For each patient, we documented CRP and ESR values at 3 different time points: firstly, at the time of the initial diagnosis; secondly, the highest value of CRP and ESR recorded during the disease course; and thirdly at the time of full assessment for this study. Cumulative inflammation over time was