Methods: Treatment was prescribed by the physician per actual clinical practice or standard of care for rheumatoid arthritis (RA), ankylosing spondylitis (AS) and psoriatic arthritis (PsA); there was no randomised assignments to treatment. There were no restrictions on the use of concomitant medications. At enrolment (baseline) and approximately every 6 months thereafter, information was collected to assess safety, clinical outcomes, quality of life, comorbidities, pharmacoeconomics and treatment regimens.

Results: A total of 1390 patients were enrolled and used for this analysis. The proportion of patients by indication was 59.2% for RA (n=890), 25.9% for AS (n=389) and 7.4% for PsA (n=111). The mean (SD) exposure was 3.10 (3.26) years for a sum of 4290.25 patient-years. Treatment with IFX was generally safe, with AEs and SAEs being reported for 64.3% and 19.5% of patients, respectively. The incidence rate of AEs and SAEs was 116.0 and 11.2 events per 100 pt-years, respectively. More specifically, 338 SAEs were reported by 189 (21.2%) RA patients [SAEs/100 pt-yrs: 11.7], 130 SAEs were reported by 60 (15.4%) AS patients [SAEs/100 pt-yrs: 10.5] and 28 SAEs were reported by 22 (19.8%) PsA patients [SAEs/100 pt-yrs: 8.82]. The most commonly reported AE identified was arthralgia, viral upper respiratory tract infection, upper respiratory tract infection and nausea. For SAEs, the most commonly reported SOC ($\geq 3\%$ of patients) was "Infections and infestations" [5.3% (n=73); 2.16 SAEs/100 pt-yrs] and "Neoplasms benign, malignant and unspecified" [3.5% (n=49); 1.24 SAEs/100 pt-yrs] which occurred at similar rates to the general RA patient population¹ and included two lymphomas [0.1%; 0.05/100 pt-yrs]. Across 3 closely monitored categories of AEs, a total of 302 closely monitored AEs were reported by 293 (21.1%) patients, including cancer (3.7%), lack of efficacy (17.1%) and tuberculosis (0.2%). A total of 21 deaths were reported during the study in 18 RA, 1 AS and 2 PsA patients. Cause of death included MACE (x5), lung cancer (x2), pulmonary fibrosis (x2), pneumonia (x2), respiratory failure, bronchitis, intestinal cancer, throat cancer, intestinal gangrene, disseminated TB, septic shock, procedural complication and drowning. The cause of death was not known for one patient.

Conclusions: The results of this longitudinal observational study showed that treatment with IFX was well tolerated in people living with AS, PsA and RA over a 15 year period in a real-world setting.

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AB0437 ADALIMUMAB THERAPY RESULTS IN SUSTAINED RESPONSE IN RHEUMATOID ARTHRITIS PATIENTS OVER 5 YEARS: THE GERMAN NONINTERVENTIONAL AGIL STUDY

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Background: Observational studies provide important insights into therapeutic response during daily clinical practice, including data on the effects of long-term treatment.

Objectives: To evaluate treatment responses in rheumatoid arthritis (RA) patients during 5 years of adalimumab (ADA) therapy.

Methods: We analysed data from a large German multicenter observational study of patients with active RA who initiated ADA therapy during routine clinical care (the AGIL study). Outcomes of interest included Disease Activity Score-28 joints (DAS28), DAS28 therapeutic response as assessed by the statistical critical difference (dcrit),¹ Health Assessment Questionnaire-Disability Index (HAQ-DI), and patient-reported global health and pain.

Results: A total of 4283 patients had data available for analysis at baseline. The mean age was 55.2 years, 74% of patients were female, the mean disease duration was 9.3 years, and 26% had received previous treatment with one or more biologic drugs. At month 60, 726 patients (17%) of patients remained in the study. During the 5 year study, 41.3% of patients were lost to follow-up, 22.3% discontinued due to lack of effectiveness (about half within the first 6 months), and 4.0% discontinued due to

adverse events. Mean values in patients treated with ADA showed a rapid response to treatment by both objective and patient-reported measures. Responses were maintained over 5 years in patients remaining on therapy (table 1). ADA was well tolerated and no unexpected safety signals were observed.

Abstract AB0437 – Table 1. Therapeutic response to ADA in the AGIL study. Values are presented as mean (standard deviation) unless otherwise indicated

	0	3	6	12	24	36	48	60
DAS28 outcomes								
n	4283	3595	3106	2532	1761	1222	906	644
DAS28	5.13 (1.15)	3.82 (1.38)	3.56 (1.36)	3.39 (1.35)	3.21 (1.32)	3.10 (1.28)	3.01 (1.21)	2.94 (1.22)
DAS28 therapeutic response (dcrit), %	—	36.7	42.7	45.9	49.7	53.7	55.3	59.5
DAS28 remission, %	0	20.3	25.9	30.1	36.8	39.2	42.7	45.2
HAQ-DI outcomes								
n	4269	3973	3409	2778	1957	1368	988	722
HAQ-DI	1.3 (0.70)	1.08 (0.73)	1.02 (0.74)	0.98 (0.74)	0.95 (0.74)	0.94 (0.73)	0.90 (0.72)	0.92 (0.71)
HAQ-DI remission, %	16.9	26.1	32.1	34.6	35.6	35.8	37.2	35.2
Patient-reported disease activity								
n	4283	3969	3442	2799	1975	1381	998	726
Patient global health*	6.05 (2.25)	4.49 (2.34)	4.24 (2.37)	4.03 (2.38)	3.76 (2.35)	3.60 (2.39)	3.46 (2.32)	3.45 (2.35)
Patient-reported pain								
n	4272	4006	3443	2796	1975	1380	998	724
Pain*	6.04 (2.27)	4.34 (2.47)	4.15 (2.46)	3.93 (2.46)	3.66 (2.41)	3.48 (2.38)	3.28 (2.39)	3.26 (2.44)

*Measured on a scale ranging from 0 (best) to 10 (worst)

Conclusions: The AGIL study is one of the largest observational cohorts to provide long-term data on ADA therapy. Both objective and subjective measures support the effectiveness and safety of ADA in patients with RA during 5 years of therapy. Approximately 43% of patients experienced a therapeutic response to treatment at 6 months as assessed by statistical methods (DAS28-dcrit),¹ and this level of response increased to 60% at 5 years in patients remaining on therapy. About one-third of patients recovered full functional ability (HAQ-DI remission) at the 6 month and subsequent visits. Our data indicate that ADA is an effective and safe long-term therapy in RA patients who continue on treatment.

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AB0438 SAFETY OF TNF BLOCKERS IN CASE OF NON-ALCOHOLIC FATTY LIVER DISEASE AND CIRRHOSIS: A SYSTEMATIC REVIEW

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Background: The management of inflammatory rheumatism and psoriasis has largely evolved over the last 15 years with the emergence of biotherapies whose main adverse effect is the increased infection risk. The prevalence of metabolic syndrome is increasing and has been estimated at 30% in patients with rheumatoid arthritis with an excess of 45% compared to healthy subjects. One of the major complications of the metabolic syndrome is the Non Alcoholic Fatty Liver Disease (NAFLD), which prevalence is 25% in the global population, and 30% in a cohort of patients with rheumatoid arthritis. The main complication of NAFLD is

the development of cirrhosis, known to increase infectious risk. Surprisingly, there are no data on the safety of TNF antagonists in patients with chronic inflammatory disease and NAFLD or cirrhosis.

Objectives: To assess infectious and liver safety of the main TNF blockers used in chronic inflammatory diseases in patients with cirrhosis or NAFLD.

Methods: A systematic review of the literature, following the Prisma recommendations, was conducted on the Pubmed and Embase databases with the following keywords: "adalimumab", "infliximab", "etanercept", "certolizumab", "golimumab" "TNF -blockers "AND" liver cirrhosis ", "non alcoholic fatty liver disease ". We selected only studies including patients treated with TNF blockers and with cirrhosis or ultrasonically characterised NAFLD. We excluded animal models and non-English articles.

Results: We identified 39 articles and only 11 fulfilled the inclusion criteria. 9 Case Reports have reported the tolerance of TNF-blockers in patients with cirrhosis and one controlled study (44 patients) assessed the safety of etanercept in case of NAFLD. One study (7 patients) investigated the impact of infliximab in refractory autoimmune hepatitis. The cause of cirrhosis was primary biliary cholangitis (5 cases), alpha1 antitrypsin deficiency (4 cases) and post hepatitis B cirrhosis (2 cases). All cirrhosis were compensated. Inflammatory diseases requiring the introduction of TNF blocker were rheumatoid arthritis (n=5), psoriatic arthritis (n=4), ulcerative colitis (n=2) and psoriasis (n=44). The TNF-blockers prescribed were adalimumab in 2 patients, infliximab in 11 patients and etanercept in 49 patients. The duration of treatment ranged from 6 to 24 months. For the 9 cirrhotic patients with an inflammatory disorder, no infection was reported and two of them (2 cases of primary biliary cholangitis) even had an improvement in liver function secondary to the introduction of biotherapy. For the 7 patients receiving infliximab to treat auto-immune hepatitis, 5 patients presented recurrent infections. For patients with NAFLD, no infectious event was reported and an improvement of the hepatic biological parameters was observed, suggesting an improvement in liver function.

Conclusions: The results of this review suggest that in case of compensated cirrhosis, TNF-blockers were not deleterious for the liver and did not increase the infectious risk. In case of auto-immune cirrhosis, TNF-blockers increased the infectious risk. In case of NAFLD, TNF-blockers might improve liver function and prevent fibrosis.

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AB0439 TRAVELLING WITH ARTHRITIS: A CROSS-SECTIONAL ANALYSIS OF DANISH ARTHRITIS PATIENTS TREATED WITH BIOLOGICS

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Background: The development and introduction of biologics has rapidly revolutionised the therapeutic approach of chronic inflammatory diseases. Well-treated patients have high physical activity levels and long life expectancy. They travel widely for holiday, business or family visits. Biological drugs are administered either intravenously or subcutaneous and have to be kept cool.

Objectives: To describe the travel patterns, the extent of pre-travel advice, travel insurance, vaccinations, adherence to biological treatment, and self-reported health related problems encountered by rheumatology patients in biologic treatment during their travel.

Methods: A cross-sectional study was conducted in an out-patient clinic at the Department of Rheumatology, North Denmark Regional Hospital. During 2017 a questionnaire with focus on travel history was distributed to 300 consecutive arthritis patients treated with biologics.

Results: A total of 273 (91%) completed the questionnaire. Median age was 67 years, and 53% were females. Overall 64% of them were receiving subcutaneous (sc) and 28% intravenous (iv) treatment, while in 8% administration route were not stated. Overall 15% of patients reported reduced travel activity after having started biologics and 21% reported that biological treatment or disease have directly influenced their decision about travelling. A total of 74% of patients have travelled outside of Denmark and 45% of these have travelled outside of Europe while treated with biologics. Pre-travel advice was sought by 26% and travel insurance was taken out by 86% of the travellers. However, 59% did not inform the insurance company about their disease or biologics. Only 6% of the travellers have experienced minor health problems which were not related to arthritis, while three patients were hospitalised. Overall 10% of patients were given additional travel vaccination. Patients, receiving sc biologics travelled significantly more than those, receiving iv treatment: 68% versus 21% (p<0.05). Overall 42% of the travellers in sc treatment group continued to take biologics during their travel, 21% had stopped the treatment before and 5% during the travel. A large proportion (72%) of travellers, who discontinued

sc treatment prior to travelling, stopped the medication due to concerns about carrying biologics in general.

Conclusions: Biological treated patients with rheumatic diseases travel frequently. Neither health-related problems nor treatments were reported to be major problems. The main problems were failure to seek pre-travel advice, worry for carrying biologics and the lack of disclosure regarding biologic treatment while seeking travel insurance. Patients receiving subcutaneous biological treatment travelled significantly more often than patients treated with intravenous biologics.

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AB0440 ETHNIC MINORITIES EXPERIENCE INFREQUENT BIOLOGIC SWITCH DESPITE ACTIVE RHEUMATOID ARTHRITIS DISEASE

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Background: The expanded therapeutic modalities in rheumatoid arthritis (RA) provide options to achieve low disease activity or remission. Yet, in routine care, the frequency and choice of switching of biologic DMARD (bDMARD) amongst ethnic subsets when there is inefficacy, is unknown.

Objectives: To evaluate frequency and choice of biologic switch in ethnic RA subsets

Methods: Patients enrolled in the Ethnic Minority RA Consortium (EMRAC), with at least one followup visit were analysed. Data included clinical outcomes as assessed by RAPID3 tender/swollen joint counts; medication use (prednisone, methotrexate, other DMARD), and bDMARD (Tumour Necrosis factor inhibitors (TNFi) and non-TNFi). Minimally clinical improvement (MCI) in RAPID3 was defined as a decrease of ≥ 3.2 points during followup. Differences between medication usage, biologic switch, and RAPID3 improvement between race and ethnicity groups while on biologics, was investigated.

Abstract AB0440 – Table 1. Demographic and clinical features of EMRAC cohort by race group

	White	African-American	Hispanic	Other	Total
N	366	252	158	264	1040
Age (years)	55.4 (15.8)	56.5 (14.5)	54.4 (13.5)	53.9 (16.3)	55.1 (15.3)
Education (years)	15.1 (3.2)	13.4 (3.2)	12.6 (4.5)	15.2 (3.5)	14.2 (3.6)
Female [N(%)]	286 (78%)	208 (83%)	126 (80%)	218 (86%)	838 (81%)
Followup (weeks)	57.0 (53.0)	92.8 (87.6)	48.7 (45.0)	52.2 (50.5)	63.2 (63.9)
RAPID3 [0–30]	11.3 (7.2)	12.9 (7.1)	12.6 (7.7)	10.8 (7.5)	11.9 (7.3)
Tender Joints [0–28]	1.0 (3.6)	2.5 (5.0)	2.4 (4.9)	0.5 (2.4)	1.5 (4.1)
Swollen Joints [0–28]	0.5 (2.0)	2.0 (3.8)	1.7 (3.9)	0.3 (1.8)	1.0 (2.9)
Prednisone Use [N(%)]	130 (36%)	89 (35%)	66 (42%)	78 (30%)	363 (35%)
Methotrexate Use [N (%)]	207 (57%)	130 (52%)	92 (58%)	160 (61%)	589 (57%)
Other DMARD Use [N (%)]	102 (28%)	74 (29%)	60 (38%)	101 (38%)	337 (32%)
Any Biologic Use [N (%)]	198 (54%)	84 (33%)	56 (35%)	105 (40%)	443 (43%)
TNF Use [N(%)]	160 (44%)	71 (28%)	41 (26%)	90 (34%)	362 (35%)
Non-TNF Use [N(%)]	54 (15%)	16 (6%)	16 (10%)	25 (9%)	111 (11%)

TNF: adalimumab, certolizumab, etanercept, golimumab, infliximab

Non-TNF: abatacept, anakinra, tocilizumab, tofacitinib, rituximab