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

F. Behrens¹, M. Schmalzing², M. Koehm¹, E.C. Schwaneck², G. Greger³, T. Mosch³, H. Burkhardt¹, H.-P. Tony². ¹Rheumatology, Goethe-University Frankfurt, Frankfurt am Main; ²Rheumatology/Immunology, Universitätsklinikum Würzburg, Würzburg; ³AbbVie Deutschland, Wiesbaden, Germany

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

F. Verhoeven^{1,2}, D. Weil-Verhoeven^{3,4}, T. Thevenot^{3,4}, C. Prati^{1,2}, V. Di Martino^{3,4}, D. Wendling^{1,4}. ¹Rheumatologie, CHRU de Besançon; ²EA 4267 PEPITE, Université de Bourgogne Franche Comté; ³Hepatology, CHRU de Besançon; ⁴EA 4266 EPILAB, Université de Bourgogne Franche Comté, Besançon, France

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