Figure 1: evolution of DAS44 in overall groups (A), TCZ patients (B) and ABA patients (C), and between Maintenance arm (M-arm) and Spacing arm (S-arm)

Figure 2: relapse-free (1) and durable relapse-free (2) survival in overall (A), TCZ (B), and ABA (C) populations and between Maintenance arm (M-arm) and Spacing arm (S-arm)

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FRI0101

NON-MEDICAL SWITCHING FROM ORIGINATOR TO BIOSIMILAR ETANERCEPT – NO EVIDENCE FOR A RELEVANT NOCEBO EFFECT – A RETROSPECTIVE ANALYSIS OF REAL-LIFE DATA

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Background: Real-world data about switching patients from originator product to a biosimilars are important to assess and to document the outcome of switches in clinical practice in order to confirm the low risk of major problems. It has been hypothesized that lack of efficacy and adverse drug events (ADEs) upon switching from reference biologics to biosimilar products are related to the nocebo effect [1].

Objectives: To evaluate the effectiveness and safety of systematic non-medical switching from innovator etanercept to biosimilar etanercept SB4 in adult patients with rheumatoid arthritis (RA), psoriatic arthritis (PsA) or axial spondyloarthritis (axSpA) in a real-life setting based on different information strategies before switching.

Methods: Data of all adult patients with rheumatoid arthritis (RA), psoriatic arthritis (PsA) or axial spondyloarthritis (axSpA) who had received innovator etanercept and were switched in our specialized center from innovator to biosimilar etanercept for economic reasons were retrospectively analysed. Whether or not patients were informed about the switch was left to the discretion of the treating physician. Disease activity and function were regularly assessed, and any changes were recorded in two consecutive visits at week 12 and 24. The scores documented at week 12 week after switching were taken as primary outcome. AEs were documented.

Results: A total of 84 patients were included (44 RA, 25 axSpA and 15 PsA patients), 24 of which had received information about switching (28.5%). The scores at week 12 of both, disease activity and function, remained rather unchanged (Table 1). Whether patients had been informed about switching or not did not influence outcomes or AE. The retention rate of the biosimilar was 96.4% (n=81) at week 12 and 87.6% (n=71) at week 24 (Figure 1). While 7 patients were lost to follow-up, 6 patients discontinued due to inefficacy or AE, including one malignant melanoma. Overall, 18 AEs were reported in 10 patients (12%). In 3 patients (3.6%) who had 5 AEs in the first 12 weeks the innovator was successfully re-administered.

Conclusion: Systematic switch from innovator to biosimilar etanercept was not associated with changes in disease activity or function in all three indications within 12 weeks. This was independent of information on the switch transmitted to the patients.

Table 1. Patient characteristics

	Assessment	Baseline (n=84)	Follow-up 12 weeks (n=81)	Follow-up 24 weeks (n=74)
RA	DAS28	3,1 (1,4)	2,8 (1,0)	3,1 (1,3)
	HAQ	1,2 (0,7)	1,3 (0,7)	1,3 (0,7)
	CRP (mg/dl)	0,5 (0,6)	0,6 (0,8)	0,7 (0,9)
PsA	DAS28	2,9 (1,4)	1,9 (1,4)	2,8 (1,5)
	HAQ	0,8 (0,5)	0,9 (0,9)	0,9 (0,9)
	CRP (mg/dl)	0,4 (0,5)	0,6 (0,6)	0,6 (0,5)
axSpA	BASDAI	4,8 (2,5)	5,0 (2,5)	4,7 (2,4)
	ASDAS	2,6 (1,3)	2,7 (0,9)	2,7 (0,8)
	BASFI	5,3 (2,7)	5,5 (2,7)	4,9 (2,8)

*Values are mean ± standard deviation

Figure 1. Retention of biosimilar stratified for patients with and without information.

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- [1] Kristensen, L.E., et al., *Non-pharmacological Effects in Switching Medication: The Nocebo Effect in Switching from Originator to Biosimilar Agent*. BioDrugs, 2018. 32(5): p. 397-404.

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FRI0102

GOLIMUMAB IMPROVES WORK PRODUCTIVITY AND ACTIVITY AND QUALITY OF LIFE IN PATIENTS WITH RHEUMATOID ARTHRITIS (RA), ANKYLOSING SPONDYLITIS (AS) AND PSORIATIC ARTHRITIS (PSA): FINAL RESULTS FROM A NON-INTERVENTIONAL STUDY IN GERMANY (GO-ART)

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Background: Golimumab (GLM) has shown its efficacy and tolerability in various randomized clinical trials. Systemic data for GLM regarding health-economic parameters in daily clinical practice are essential not only for pharmaceutical companies but also for cost-benefit analyses in Germany.

Objectives: This prospective NIS was designed to evaluate the impact of GLM therapy on work productivity and activity as well as Quality of Life (QoL) in patients with RA, AS or PsA in Germany under routine settings over an observation period of 12 months, plus an additional voluntary extension period of 12 months (total 24 months) to collect long-term data on health economic parameters.

Methods: GO-ART was an observational prospective study on patients with RA, AS or PsA (biologic-naïve and biologic-experienced) who started treatment with GLM at 63 sites of Germany.

The primary endpoint was the change in work productivity/activity impairment as measured by Work Productivity and Activity Impairment (WPAI) questionnaire from baseline, measured primarily at month 3 and secondarily at months 6, 12 and 24.

As secondary endpoint the change in quality of life (RAQoL for RA patients, ASQoL for AS patients and NAPPA-QoL for PsA patients) was assessed.

Results: 748 patients (RA=250, PsA=249, AS=249) started GLM therapy. The primary efficacy endpoint was analyzed in the modified intention-to-treat (mITT) subset of 493 patients (RA=158, PsA=157, AS=178) with full-time or part-time employment at baseline (mITTe).

A total of 348 patients entered the additional 12-month observation period, of which 303 completed the 24-month assessment.

By 3 months after initiation of Golimumab treatment, a marked improvement was seen in all 4 WPAI domain scores ("absenteeism" (time off work), "presenteeism" (on-the-job productivity), "total work productivity impairment" (TWPI), and "activity impairment") in daily living because of patient's health problems related to RA, PsA or AS, as shown in Table 1 (all p-values <0.05).

The statistically significant improvements in the mean WPAI domain scores were maintained over the 24-month observation period in all 3 indications with a higher treatment effect regarding "activity impairment" and "presenteeism" compared to "absenteeism" (Table 1).

Quality of life improved significantly (p<0.0001) from baseline at month 3, 6, 12 and 24 in patients with RA (RAQoL), AS (ASQoL) and PsA (NAPPA-QoL) based on questionnaire data of 237 RA patients (RA-mITT), 228 AS patients (AS-mITT) and 235 PsA patients (PsA-mITT) indicating a clinically relevant improvement.

Conclusion: Treatment with GLM provided sustained improvement in WPAI and QoL in patients with RA, PsA and AS over the observational period of 24 months.

All scores of the WPAI showed a significant (p< 0.05) reduction in mean score values in each indication.

GLM leads to an improvement of work productivity and daily activities in patients already within the first 3 months of treatment.

Table 1:

WPAI - Changes in the 4 domain scores from baseline to Months 3, 12 and 24 (mITTe)

Timepoint	Statistics	Total work productivity impairment	Absenteeism	Presenteeism	Activity impairment
RA patients (mITTe: N=158)					
V0 (baseline)	N	108	135	113	154
	Mean	46.8	11.9	46.0	50.9
	SD	27.60	30.80	27.76	28.36
Change in scores:					
V0 - V1 (Month 3) (primary endpoint)	N	78	110	83	133
	Mean	-11.3	-5.8	-12.5	-13.9
	SD	23.77	29.37	23.00	26.77
	p-value	<0.0001 ¹	0.0429 ²	<0.0001 ¹	<0.0001 ¹
V0 - V3 (Month 12)	N	67	89	75	114
	Mean	-13.2	-8.8	-12.7	-15.2
	SD	23.40	36.51	22.08	24.23
	p-value	<0.0001 ¹	0.0128 ²	<0.0001 ¹	<0.0001 ¹
V0 - V6 (Month 24)	N	43	55	45	67
	Mean	-13.7	-7.8	-12.2	-18.4
	SD	25.64	30.73	26.10	26.32
	p-value	0.0012 ²	0.0647 ²	0.0030 ²	<0.0001 ¹
PsA patients (mITTe: N=157)					
V0 (baseline)	N	114	137	115	153
	Mean	35.0	12.9	33.4	43.2
	SD	27.77	30.87	26.42	28.45
Change in scores:					
V0 - V1 (Month 3) (primary endpoint)	N	81	109	85	128
	Mean	-13.8	-4.9	-15.4	-17.4
	SD	25.02	28.33	25.98	30.44
	p-value	<0.0001 ¹	0.0449 ²	<0.0001 ¹	<0.0001 ¹
V0 - V3 (Month 12)	N	77	99	80	118
	Mean	-10.6	-4.6	-12.7	-18.3
	SD	30.40	30.62	27.82	30.28
	p-value	0.0046 ²	0.2028 ²	0.0001 ¹	<0.0001 ¹
V0 - V6 (Month 24)	N	39	48	41	63
	Mean	-9.5	-1.9	-16.5	-23.4
	SD	29.99	31.56	25.64	31.36
	p-value	0.0472 ²	0.6084 ²	0.0003 ²	<0.0001 ¹
AS patients (mITTe: N=178)					
V0 (baseline)	N	136	160	142	177
	Mean	48.2	14.0	45.9	52.1
	SD	28.08	29.55	26.74	25.87
Change in scores:					
V0 - V1 (Month 3) (primary endpoint)	N	104	135	111	162
	Mean	-16.9	-8.9	-15.8	-18.3
	SD	26.62	30.73	24.66	26.43
	p-value	<0.0001 ¹	0.0001 ¹	<0.0001 ¹	<0.0001 ¹
V0 - V3 (Month 12)	N	93	120	100	130
	Mean	-16.8	-6.1	-16.1	-22.8
	SD	31.92	31.46	30.45	28.77
	p-value	<0.0001 ¹	0.0141 ²	<0.0001 ¹	<0.0001 ¹
V0 - V6 (Month 24)	N	46	64	50	72
	Mean	-24.7	-14.1	-22.0	-28.3
	SD	32.71	33.29	28.54	29.79
	p-value	<0.0001 ¹	0.0002 ²	<0.0001 ¹	<0.0001 ¹

AS = Ankylosing Spondylitis; PsA = Psoriatic Arthritis; RA = Rheumatoid Arthritis
WPAI = Work Productivity and Activity Impairment
Total work productivity impairment = Overall impairment estimate calculated by an algorithm of absenteeism and presenteeism.
Absenteeism = Percentage of work time missed because of patient's health problem in the past 7 days.
Presenteeism = Percentage of impairment experienced while at work in the past 7 days because of patient's health problem.
Activity impairment = Percentage of impairment in daily activities because of patient's health problem in the past 7 days

¹t-test; ²Wilcoxon Signed rank test

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FRI0103

BENEFIT STUDY: A PAN-EUROPEAN OBSERVATIONAL STUDY TO EVALUATE REAL-WORLD EFFECTIVENESS OF SB4 FOLLOWING TRANSITION FROM ORIGINATOR ETANERCEPT (ETN) IN PATIENTS WITH RHEUMATOID ARTHRITIS (RA) OR AXIAL SPONDYLOARTHRITIS (AXSPA)

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Background: Having demonstrated bioequivalence and similar efficacy, safety and immunogenicity as the originator, SB4 is approved in the EU