Adverse events were well matched between the adalimumab treatment arm and placebo during the placebo-controlled period. After two years of treatment 14 patients were still receiving study drug. Reasons for drop out were lack of efficacy (4 pts), adverse events (3 pts), death (1 pt on placebo, 1 on adalimumab, both myocardial infarction), and protocol violation (1 pt).

Abstract OP0083 Table 1

	Baseline	6 mo	12 mo	18 mo	24 mo
% pts EULAR response		91	78	78	74
% pts ACR 20		78	65	65	61
% pts ACR 50		26	26	35	35
DAS*	5.23	3.46	2.78	2.49	2.60
Ritchie Index*	18.0	6.0	4.0	3.0	4.0
SJC [0–44 joints]*	20.0	5.0	2.0	4.0	2.0
CRP [mg/L]*	35.0	19.8	13.5	9.6	11.8

*median.

Conclusion Repeated weekly s.c. injections of a dose of 0.5 mg/kg or 1 mg/kg adalimumab (D2E7) given to patients with active rheumatoid arthritis over a period of two years were efficacious and well tolerated.

OP0084 PEG STNF-RI IMPROVES HEALTH-RELATED QUALITY OF LIFE IN PATIENTS WITH RHEUMATOID ARTHRITIS

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Background

Objectives To evaluate the effect of PEG sTNF-RI on the health related quality of life (HRQOL) of subjects with rheumatoid arthritis.

Methods In a 12-week, multicenter, randomised, double-blind clinical trial, 194 subjects received either 400- or 800-mcg/kg of PEG sTNF-RI or placebo SC weekly (1:1:1). The study population included subjects with or without background DMARDs (combination therapy involving methotrexate with sulfasalazine or hydroxychloroquine, or sulfasalazine plus hydroxychloroquine). To measure HRQOL, the SF-36 was administered at baseline and at weeks 4 and 12. The SF-36 consists of 36 items designed to assess physical function (PF), role limitations due to physical problems (RP), body pain (BP), general health (GH), vitality/energy (VT), social function (SF), role limitations due to emotional problems (RE), and mental health (MH). The SF-36 is scored from 0 to 100, with higher scores indicating better HRQOL. Differences of 3 to 5 points are considered clinically and socially relevant. The mean change in each SF-36 scale score was compared between subjects receiving PEG sTNF-RI and those on placebo using a repeated measure mixed effect model analysis. The analysis set was a modified intent-to-treat sample, i.e. all patients who received at least one dose were included (n = 193).

Results Subjects using either dose of PEG sTNF-RI experienced statistically significant, and clinically and socially relevant improvements in each SF-36 scale (see Table 1). These improvements exceeded those for subjects on placebo in every scale and

were statistically significantly improved over placebo for 7 of 8 scales for the 800-mcg/kg dose, and 6 of 8 scales for the 400-mcg/kg dose.

Abstract OP0084 Table 1 Mean change in SF-36 scales from baseline to week 12

Dose of PEG sTNF-RI	PF	RP	BP	GH	VT	SF	RE	MH
800 mcg/kg (n = 66)	12.5*	25.4*	22.0*	7.0	16.9*	13.2*	19.8*	5.2*
400 mcg/kg (n = 67)	8.2	24.3*	14.7*	9.4*	13.9*	12.8*	14.3	6.8*
Placebo (n = 61)	4.8	6.1	6.0	2.2	6.7	1.3	0.8	-1.3

*p < 0.05 for comparison with placebo.

Conclusion Subjects receiving PEG sTNF-RI experienced statistically significant, clinically and socially relevant improvements in their SF-36 scores. These improvements occurred across a full range of health-related quality of life scales, from the physical to the psychosocial, and exceeded those for subjects on placebo. In this population of patients with rheumatoid arthritis, some of whom received DMARD or combination DMARD therapy, PEG sTNF-RI leads to significant and meaningful improvements in health-related quality of life.

OP0085 INFILIXIMAB PLUS METHOTREXATE IMPROVES SIGNS AND SYMPTOMS IN INITIAL NON-RESPONDERS WHO CONTINUE TREATMENT

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Background In an international, placebo-controlled, randomised trial, 428 patients with active RA despite methotrexate (MTX) therapy received placebo (i.e. MTX alone) or infliximab at 3 mg/kg or 10 mg/kg every 4 or 8 weeks along with MTX for 102 weeks. In this trial, infliximab plus MTX improved signs and symptoms, inhibited progression of structural damage, and improved physical function compared to MTX alone.

Objectives To determine if continued treatment with infliximab benefits patients who are not ACR20 responders at week 30.

Methods Patients who were not responders according to ACR20 criteria at week 30 were identified. Their clinical response to continued treatment was assessed based on ACR-N at the week 54 and week 102 visits. Analysis of variance on the van der Waerden normal scores was used to compare the ACR-N values at these time points. Radiologic response is based on the modified total Sharp score (TSS).

Results The ACR-N and change in TSS at weeks 30, 54 and 102 are shown in the Table 1. The ACR-N was higher in the infliximab treated groups, compared to the placebo treated group at weeks 54 and 102. The change in TSS was higher at all time points in the placebo group as compared to the infliximab treated groups.

Conclusion Patients who did not initially benefit from infliximab treatment derived clinical benefit when they continued to be treated long-term. Radiographic benefit was noted over time in all of the infliximab treated groups. The time point at which patients can be categorised as clinical non-responders to infliximab therapy needs further examination.