CRP) <2.6, Clinical Disease Activity Index (CDAI) <2.8 and Simplified Disease Activity Index (SDAI) <3.3.

Results: A total of 418 patients were randomized and received treatment. Baseline characteristics were balanced across the arms; 82% female, mean age 50 years, mean duration of RA 5.9 years, mean DAS28 (CRP) 5.94, and 80% rheumatoid factor positive. The primary endpoint was met; ACR 20 response rates were statistically significantly higher in all CLZ arms versus pbo + MTX. All CLZ treatment groups were associated with improved ACR 20/50/70 response rates, HAQ-DI and remission versus pbo + MTX through Week 24. Rates of remission per DAS28 (CRP) <2.6, SDAI <3.3 and CDAI <2.8 were numerically higher in the CLZ + MTX arms compared with ADA + MTX. Treatment with CLZ in combination with MTX resulted in higher response rates than monotherapy. However, no clear dose response for efficacy was noted. The rates of serious adverse events ranged from 8.3 to 13.3% in CLZ arms versus 3.3% for pbo + MTX and 5.1% for ADA + MTX. Rates of serious infections were similar as reported for all CLZ arms and ADA versus none in pbo. CLZ was associated with mostly mild injection-site reactions, few of which led to discontinuation. As expected based on its mode of action, CLZ treatment was associated with increased transaminases (mainly in combination with MTX), increased lipids and haemoglobin, and decreased polymorphonuclear neutrophils and platelets.

Conclusions: Clazakizumab as monotherapy or in combination with MTX demonstrated efficacy in controlling the signs and symptoms of RA. At Week 24, remission rates with clazakizumab + MTX trended higher than with ADA + MTX. Its safety profile was consistent with the known pharmacology of IL-6 blockade. Clazakizumab is a promising future treatment for RA that warrants further investigation.

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SAT0245 DECREASED USE OF GLUCOCORTICOIDS IN PTS WITH RA WHO INITIATED IV ABATACEPT AND PREVIOUSLY FAILED AT LEAST ONE BIOLOGIC AGENT: RESULTS FROM THE 2-YEAR ACTION STUDY

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Background: EULAR recommends initiation of biologic agents in combination with MTX in pts with RA after failure of conventional synthetic (cs)DMARDs and in the presence of poor prognostic factors. In addition, low-dose glucocorticoids should be considered as part of the treatment strategy, but should be tapered as rapidly as is clinically feasible.[1]

Objectives: To assess changes over 2 yrs in concomitant treatment strategy with csDMARDs and, more specifically, glucocorticoids in pts with RA who initiated IV abatacept (ABA) and had previously failed ≥1 biologic agent in the real-world ACTION study.

Methods: ACTION is a 2-year, international (Austria, Belgium, Canada, Czech Republic, Denmark, Germany, Greece, Italy, the Netherlands), non-interventional cohort of pts with RA who initiated IV ABA between May 2008 and January 2011. At each clinical visit, changes in concomitant treatments were collected, including changes in dosage. The use of concomitant treatments is reported at ABA initiation and at 24 mths for pts who remained on ABA at 24 mths.

Results: Among 1131 evaluable pts, 1009 failed ≥1 biologic agent. Of these pts, ABA was initiated as monotherapy in 237/1009 (23.5%) pts and in combination with a csDMARD in 772/1009 (76.5%) pts. At baseline, glucocorticoids were used by 734/1009 (72.7%) pts (median dose: 7.5 mg; n=692). Concomitant DMARD and glucocorticoid use was assessed in 407/1009 (40.3%) pts who were on abatacept at 24 mths and had available data. Of these pts, ABA was initiated as monotherapy in 88/407 (21.6%) pts and in combination with csDMARDs in 319/407 (78.4%) pts. There was no change in treatment strategy at 24 mths in 348/407 (85.5%) pts. Over 24 mths, csDMARDs were initiated in 21/407 (5.2%) pts and were stopped in 38/407 (9.3%) pts; mean MTX dose remained stable (approximately 14 mg/wk). The proportion of pts who received glucocorticoids and the corresponding median dose decreased from 301/407 (74.0%) pts (median dose: 6.5 mg; dose available in 284 pts) at baseline to 237/407 (58.2%) pts (median dose: 5 mg; dose available in 232 pts) at 24 mths. Over 24 mths, glucocorticoids were initiated in 16/407 (3.9%) pts (median dose: 5 mg) and were stopped in 80/407 (19.7%) pts; glucocorticoid dose decreased in 88/216 (40.7%) pts and increased in 19/216 (8.8%) pts when doses were available.

Conclusions: The majority of pts who initiated IV abatacept remained on the same csDMARD treatment strategy (monotherapy or combination) at 24 mths. The proportion of pts who received glucocorticoids and the corresponding glucocorticoid dose decreased over 24 mths, in line with the 2013 update of the EULAR recommendation that glucocorticoids should be tapered as rapidly as is clinically feasible to reduce the risk of side effects.[1]

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SAT0246 CORRELATION OF CLINICAL RESPONSE WITH PATIENT-REPORTED OUTCOMES IN THE AMPLE (ABATACEPT VERSUS ADALIMUMAB COMPARISON IN BIOLOGIC-NAÏVE RA PATIENTS WITH BACKGROUND METHOTREXATE) TRIAL: 2-YEAR RESULTS

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Background: RA is a progressively debilitating disease that decreases health-related quality of life and increases functional limitation of daily living activities. Year 1 and 2 data from the 2-year head-to-head AMPLE study showed comparable improvements and similar onset of response with subcutaneous (SC) abatacept (ABA) and adalimumab (ADA) on background MTX across multiple clinical measures and patient-reported outcomes (PROs).[1,2] It is important to understand the association between clinical responses and improvements in pain, fatigue and the ability to perform work and daily activities.

Objectives: To use 2-year data from the AMPLE trial to examine correlations between clinical response, including stringent remission parameters, and PROs.

Methods: AMPLE is a Phase IIIb, randomized, investigator-blinded study. Biologic-naïve patients (pts) with RA and an inadequate response to MTX were randomized to SC 125 mg ABA weekly or 40 mg ADA bi-weekly, with background MTX. The proportions of pts achieving low disease activity (LDA; Clinical Disease Activity Index [CDAI] ≤10, Simplified Disease Activity Index [SDAI] ≤11) or remission (CDAI ≤2.8, SDAI ≤3.3, Boolean score ≤1) were assessed. PROs were analysed for pts who obtained these clinical responses at both Years 1 and 2 ("responders") and those who did not ("non-responders"). Pain and fatigue were measured by 100-mm visual analogue scales (VAS). Work productivity was assessed using the Work Productivity and Activity Impairment (WPAI) questionnaire. The Activity Limitation Questionnaire measured the number of days pts were unable to perform usual activities during the prior 30 days.

Results: 646 pts were randomized and treated with SC ABA (n=318) or ADA (n=328) on background MTX. Baseline characteristics were balanced between the two treatment arms. Across multiple measures, greater improvements were observed in pain, fatigue, work time and activity in those achieving LDA or remission (Table 1).

Conclusions: Achievement of clinical remission and LDA was associated with greater improvements in PROs (pain, fatigue and the ability to perform work and

Table 1

Clinical measure	n		Mean improvement from baseline at Year 2							
			Pain (100-mm VAS)		Fatigue (100-mm) VAS)		Work time (days gained)		Activity (days gained)	
	ABA	ADA	ABA	ADA	ABA	ADA	ABA	ADA	ABA	ADA
CDAI LDA										
Responder	138	137	44	43	32	30	10	10	9	8
Non-responder	65	61	25	23	17	16	4	–1	4	2
CDAI remission										
Responder	46	45	50	50	33	34	14	13	8	8
Non-responder	155	152	31	30	20	21	7	4	6	5
SDAI LDA										
Responder	139	138	45	43	31	30	10	11	8	8
Non-responder	63	55	27	23	18	16	4	2	4	2
SDAI remission										
Responder	46	47	50	49	33	34	13	12	8	7
Non-responder	157	146	31	29	20	19	7	3	6	5
Boolean remission										
Responder	24	27	49	47	38	35	12	13	6	5
Non-responder	189	180	34	31	23	21	8	4	7	5

daily activities) than pts who did not achieve clinical response. Pts treated with SC abatacept and adalimumab over 2 years had comparable responses.

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SAT0247 SAFETY OF RAPID RITUXIMAB INFUSION IN RHEUMATOID ARTHRITIS IN A SINGLE COMMUNITY PRACTICE

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Background: Rituximab, a chimeric monoclonal anti-CD20 antibody, is approved to be infused over 4hours and 15minutes, due to the potential for infusion reactions. The risk of infusion reactions has been shown to be greatest with the first infusion. Previously we reported our experience with rapid rituximab infusion in 10 rheumatoid arthritis patients, receiving a total of 26 rapid infusions. We now report a current safety analysis of 28 patients receiving a total of 132 rapid infusions in a single rheumatology practice.

Objectives: To evaluate the safety, tolerability, and practicality of a rapid-infusion protocol for rituximab in RA patients (n=28) in a single community setting.

Methods: Patients, who were prescribed Rituximab for treatment of moderate to severe RA, were recruited from October 2006 to November 2013 and given the opportunity to participate in the rapid infusion protocol. All patients provided written informed consent. Each treatment course consisted of two rituximab 1000mg infusions, give 2 weeks apart. The first infusion followed the conventional infusion schedule. Rapid infusion protocol was administered on second and/or all subsequent infusions over 2hours. All patients received premedication. Vital signs were recorded at baseline and at 15, 30, 60, 90 and 120minutes.

Results: A total of 57 patients received rituximab infusions (280 infusions) from October 2006 to November 2013. Out of these, 50 patients with a diagnosis of rheumatoid arthritis met the criteria to be followed on the short infusion protocol. A total of 28 patients agreed to be followed on the rapid rituximab infusions. 132 infusions were included in this analysis with the mean treatment interval of 9.4 months. 93% of the patient population had failed or were intolerant to prior TNF-α inhibitors and 7% were biologic naïve.

A total of 7 infusion reactions were reported over 132 rapid rituximab infusions (28 patients), as compared to 8 infusion reactions over 148 conventional infusions (22 patients). There was no significant difference in the incidence of infusion reactions between rapid and conventional infusion (p=0.97). In both rapid and conventional infusions, no patients discontinued rituximab due to infusion-related symptoms and reactions. Overall, all symptoms reported were mild and resolved within 24 hours after the infusion. No serious infections or serious adverse events were reported in both short and conventional infusion groups.

Conclusions: The current analysis provides reassurance that rapid rituximab infusion is safe and well tolerated. Our experience of administering this protocol over seven years proves that rapid infusion is as safe as the conventional infusion. In addition to safety, patients reported greater satisfaction with the short infusion duration. These data and previously reported data on rapid infusion in rheumatoid arthritis patients assure physicians that this strategy can be safely implemented in an infusion clinic setting.

Disclosure of Interest: None declared

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SAT0248 BIOLOGIC THERAPY IMPROVES THE NUMBER OF PATIENTS WHO MAINTAIN EMPLOYMENT AND IMPROVES THEIR OVERALL FUNCTION

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Background: Rheumatoid arthritis (RA) is a chronic disease that causes significant disability impacts health related quality of life and is a major economic burden. Many studies have shown RA to be associated with absenteeism, job loss, and impairment in work productivity. Biologic therapies have improved the management of RA through marked reductions in the manifestations of RA and improvement of function.

Objectives: A cross sectional survey was carried out using our biologics database to evaluate the impact of biologics on employment in a cohort of patients with Rheumatoid arthritis.

Methods: A patient-self-reported questionnaire was developed in conjuction with a patient expert group to assess the work status at the onset of their disease, onset of biological treatment and current work status. Time from diagnosis to first biologic was evaluated, as was smoking status. Patients were also asked about the current impact of RA on their life and how biologic therapy had improved their arthritis. Patients were randomly chosen to receive this questionaire.

Results: Of the 100 questionnaires distributed, 93 were completed and returned. 27% were male, and 22.5% were current smokers. The mean time from diagnosis to first biologic was 8 years. At diagnosis, 46% were in full-time employment, 26% part-time employment, 15% were retired, and 10% were unable to work due to rheumatoid arthritis or other medical condition. At the start of biologic therapy, 29% were in full time employment, 19% in part time employment, 28% were retired, and 21.5% were unable to work due to RA. At present, 29% remain in full time employment, 23% in part time employment, 31% retired, and only 13% were unable to work due to RA. 53% reported that their arthritis was much better since starting their biologic, and 38% said their arthritis was better. Patients in full time employment had a shorter time before first biologic (mean 6 years), patients unable to work due to their arthritis had a longer time to their first biologic (10.1 years).

Conclusions: Patients with RA who received biologic therapy remained in full or part time employment and the number of patients unable to work was reduced. Patient satisfaction with their health state also improved with biologic therapy. Earlier biologic therapy improves their ability to retain employment.

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SAT0249 TOCILIZUMAB IN THE TREATMENT OF PATIENTS WITH RHEUMATOID ARTHRITIS IN REAL CLINICAL PRACTICE: RESULTS OF TRUST STUDY

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Background: Tocilizumab (TCZ) is an interleukin-6 receptor inhibitor for treatment of patients (pts) with moderate to severe rheumatoid arthritis (RA) and inadequate response (IR) to disease modifying anti-rheumatic drugs (DMARDs) or anti-Tumor Necrosis Factor (anti-TNF) agents.

Objectives: Describe the efficacy and safety of TCZ in pts with RA in Italian clinical practice. Primary endpoint: proportion of pts with remission or low disease activity (LDA) after 6 months of TCZ treatment.

Methods: TRUST is a multicenter, retrospective-prospective, observational study in pts with RA who had started treatment with TCZ in the 6 months prior to center opening and were still on treatment at the beginning of the study (retrospective phase); pts were then followed up to a maximum of 12 months after the first TCZ infusion (prospective phase).

Results: A total of 322 RA pts were enrolled in 59 Italian centers (mean age: 55.8 years; mean disease duration: 120.5 months; baseline DAS28: 5.3). After 6 months of TCZ treatment, the proportion of pts (57.52%, N=130, p-value$<$0.0237) achieving LDA (DAS28 $\leq$3.2) and disease remission (DAS28 $\leq$2.6; 38.05%, N=86, p-value=0.0003) out of 226 pts with available DAS28 were statistically significant vs baseline. A considerable proportion of pts (32.6%, N=105) was