who achieved BASDAI 20/50/70 response gradually increased from week 6 to week 24 or 30 in Naïve group with AS (Figure 1).

Fifty percent of naïve patients with PsA achieved clinical remission. The proportions of both PASI 50 and 75 responses were 50% at Week 22 in Naïve group and were 100% and 50% in Switch group, respectively during post-baseline visits in PS patients.

Throughout this study, treatment-emergent adverse events (TEAE) and treatment-emergent serious adverse events (TESAE) were reported as Table 2. Only 11% of patients experienced infection.

Table 1. Clinical remission in RA and AS

		Naïve		Switch	
		Baseline	Post-baseline	Baseline	Post-baseline
RA	DAS28 (ESR)	0/181 (0.0%)	24/182 (13.1%)	0/25 (0.0%)	5/25 (20.0%)
	DAS28 (CRP)	0/180 (0.0%)	43/179 (24.0%)	2/25 (8.0%)	6/24 (25.0%)
AS	BASDAI	2/292 (0.7%)	199/292 (68.2%)	112/209 (53.6%)	150/210 (71.4%)

Table 2. Summary of safety results

n/N (%)	RA	AS	PsA	PS
TEAE	198/400 (49.5)	183/531 (34.5)	1/3 (33.3)	3/6 (50.0)
TEAE related with CT-P13	73/400 (18.3)	64/531 (12.1)	0/3 (0.0)	2/6 (33.3)
TESAE	52/400 (13.0)	14/531 (2.6)	0/3 (0.0)	1/6 (16.7)
TESAE related with CT-P13	15/400 (3.8)	6/531 (1.1)	0/3 (0.0)	0/6 (0.0)
Infusion-related reactions	28/400 (7.0)	11/531 (2.1)	0/3 (0.0)	0/6 (0.0)

Figure 1. Clinical response of RA and AS

Conclusions: CT-P13 is efficacious and well-tolerated in RA/AS/PsA/PS patients. Efficacy and safety results in patients treated with CT-P13 were clinically consistent to historical data [1,2,3]. Especially, Switch group results showed that CT-P13 provides a useful alternative to other anti-TNFs.

References:

- [1] Kobayashi et al (2016).
- [2] Hetland et al (2005).
- [3] Hetland et al (2010).

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SAT0155 ADALIMUMAB IN COMBINATION WITH NON-METHOTREXATE CONVENTIONAL SYNTHETIC DISEASE MODIFYING RHEUMATIC DRUGS IN A CLINICAL TRIAL SETTING

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Background: Biologics in combination with methotrexate (MTX) are associated with improved outcomes versus monotherapy. However, few data exist regarding the use of non-MTX conventional synthetic disease modifying rheumatic drugs (csDMARDs) with biologics.

Objectives: To assess the effectiveness and safety of adalimumab (ADA) in combination with MTX and non-MTX csDMARDs through 6 months.

Methods: This post hoc analysis used data from the 24-week (wk) placebo-controlled trial of ADA (STAR), assessing safety and efficacy of ADA+csDMARDs in patients (pts) with moderate to severe RA.¹ For those pts receiving 1 csDMARD, pts were subgrouped according to csDMARD. The most frequently used csDMARDs assessed were MTX, sulfasalazine (SSZ), hydroxychloroquine (HCQ), and leflunomide (LEF). Nineteen pts who received parenteral gold in combination with ADA were excluded from this analysis. Baseline demographics and disease characteristics were summarized across csDMARD groups. 20/50/70% improvement in American College of Rheumatology (ACR) response criteria were assessed for each subgroup. Other clinical and functional endpoints were assessed using ANCOVA within subgroups as the least square (LS) means of the mean change from baseline to wk 24. Adverse events (AEs) were monitored throughout.

Results: Of the 290 pts randomized to receive ADA, 237 (82%) received ≥1 csDMARD [174 (60%) and 63 (22%) received ADA in combination with 1 and ≥2 csDMARDs, respectively]. Of the 63 pts who received ≥2 csDMARDs in combination with ADA, 55 (87%) received concomitant MTX therapy. Similarly, most of the pts receiving ADA in combination with a single csDMARD received

MTX [114 (66%)], while 60 pts received ADA in combination with a single non-MTX csDMARD. Pts receiving non-MTX csDMARDs were slightly younger, on average, than those receiving MTX (mean age: 51.4 vs 56.4 years), but demonstrated slightly higher mean HAQ-DI (1.37 vs 1.26) and CRP (2.4 vs 1.3) at baseline. Following 6 months of combination therapy, pts receiving ADA+MTX experienced numerically better clinical and functional outcomes to pts receiving ADA+non-MTX csDMARDs (Table). The lower response in the non-MTX DMARD group appeared to be driven by pts receiving LEF, who tended to experience lower levels of response in combination with ADA. Overall, frequencies of AEs were similar between combination therapy with MTX and non-MTX csDMARDs (~90% in both groups). Serious AEs were observed in 10% of pts receiving non-MTX csDMARDs and 5% of pts receiving MTX. A total of 42% in the non-MTX csDMARD and 60% in the MTX group experienced infections during the course of the study. There were 3 serious infections, all occurring in the MTX group.

Table. Week 24 Clinical and Functional Outcomes Among Patients Receiving Adalimumab in Combination With a Single csDMARD

Variable	ADA+MTX n=114	ADA+non-MTX csDMARD n=60			
		Pooled n=60	LEF n=25	SSZ n=12	HCQ n=23
ACR20	69 (61)	27 (45)	8 (32)	7 (58)	12 (52)
ACR 50	40 (35)	14 (23)	3 (12)	4 (33)	7 (30)
ACR70	22 (19)	7 (12)	0 (0)	3 (25)	4 (17)
DAS28(CRP)	-1.912 ^a	-1.923 ^b	-1.516 ^c	-1.579 ^d	-2.206 ^e
SDAI	-22.60 ^a	-22.21 ^b	-18.41 ^c	-23.80 ^d	-24.61 ^e
CDAI	-21.90 ^f	-20.95 ^g	-18.05 ^h	-23.79 ^d	-22.02 ⁱ
HAQ-DI	-0.509 ^j	-0.435 ^k	-0.251 ^l	-0.595 ^d	-0.524 ^k

Discrete variables are summarized as n (%).

All continuous variables are within group LS means in mean change from baseline to week 24 using ANCOVA, with csDMARD subgroup as a factor and baseline value as covariate, with the exception of the pooled group, which is mean change from baseline.

^an=105; ^bn=52; ^cn=20; ^dn=11; ^en=21; ^fn=106; ^gn=53; ^hn=22; ⁱn=54.

csDMARDs, conventional synthetic disease-modifying antirheumatic drugs; ADA, adalimumab; MTX, methotrexate; LEF, leflunomide; SSZ, sulfasalazine; HCQ, hydroxychloroquine; ACR, American College of Rheumatology; DAS28(CRP), 28-joint disease activity score based on C-reactive protein; SDAI, simplified disease activity index; CDAI, composite disease activity index; HAQ-DI, health assessment questionnaire disability index.

Conclusions: MTX administered in combination with biologics, like ADA, leads to superior outcomes vs monotherapy. For pts who can't tolerate MTX, non-MTX csDMARDs, specifically HCQ and SSZ but not LEF, may be good alternatives, as outcomes were largely comparable with those of pts receiving MTX when combined with ADA. The limited sample size examined in this analysis should be confirmed in a larger pt population.

References:

- [1] Furst DE, et al. J Rheum 2003;30(12):2563–71.

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SAT0156 EXPOSITION TO BIOLOGICAL THERAPY DURING PREGNANCY: A SINGLE-CENTRE STUDY OF PREGNANCY OUTCOME IN MOTHERS WITH RHEUMATIC DISEASES

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Background: Biologic DMARDs fall within the FDA category B or C. However many case series and registry data are available about women exposed during pregnancy.

Objectives: to extend information on this topic by the contribution of a tertiary single centre case series

Methods: Data were collected from a single-centre cohort of outpatients followed between 2006 and 2016. Women with rheumatic diseases (RD) exposed to biological (BE) agent during pregnancy or in the 3 months before conception were included. Outcomes in the BE group were compared with an age-matched group of pregnant women with RD non-exposed to biological agent (NE). Demographic and clinical data, obstetric outcome and neonatal complications were recorded.

Results: 34 pregnancies in 28 patients were included: 14 Rheumatoid Arthritis (RA), 6 ankylosing spondylitis (AS), 2 Psoriatic arthritis (PsA), 4 Undifferentiated spondyloarthritis (uSpA), 1 Dermatomyositis (DM), 1 Adult Onset Still's disease

(AOSD); all were exposed to a biologic agent: 16 Etanercept (ETA), 7 Adalimumab (ADA), 4 Infliximab (IFX), 1 Certolizumab (CTZ), 5 Rituximab (RTX), 1 Anakinra (ANK). Median age was 34 yrs (range 24–50). All patients treated with TNFi and ANK withdrew therapy in early pregnancy (<10 weeks gestational age). 2 RA patients had 2 pregnancies each, during ETA treatment. A RA woman became pregnant 4 times during RTX therapy. 10 patients were also on csDMARDs therapy at the time of conceptions: 7 Hydroxychloroquine (HCQ), 1 HCQ + Sulphasalazine (SSZ), 1 Cyclosporine A (CYA), which was continued, and 1 with Methotrexate which was immediately withdrawn. 1 RA patient started SSZ from the 24th week. 15 patients (7 RA, 2 PsA, 2 AS, 2 uSpA, 1 DM) started or increased oral and/or intra-articular steroids because of disease flare. A control group of 45 pregnancies observed in 42 patients not exposed to biologics was selected="selected" (19 RA, 12 uSpA, 3 Juvenile Idiopathic Arthritis (JIA), 5 PsA, 1 AS, 1 DM, 1 AOSD), median age 35 (range 22–42). 18 patients were treated with csDMARDs during pregnancy (8 HCQ; 4 SSZ; 2 CYA+HCQ; 4 SSZ+HCQ). No other drugs were taken at the time of conception, apart from low dose of steroids in 24 cases; in 1 case intra-articular steroids were given because of disease flare. Pregnancy outcomes are summarized in tab.1: therapeutic abortions were performed for an extrauterine pregnancy occurred twice in the patient with RA who became pregnant 4 times during RTX treatment, after the 5th and the 6th retreatment. After the 4th retreatment she had an early spontaneous abortion. Previously, she delivered 2 healthy children after exposure to ETA and 3 treatment cycles of RTX. No serious perinatal complication occurred, excluding very preterm baby delivery at 28th weeks, who needed neonatal intensive care. No congenital malformations were observed. Klinefelter syndrome was diagnosed in 1 case.

Tab. 1: Pregnancy outcomes of women with RD exposed to biological (BE) compared with pregnant women with RD non-exposed to biological agent (NE)

	BE group (34)	NE group (45)	p
Live births	29 (85.3%)	43 (95.5%)	ns
Spontaneous abortion	2 (5.9%)	2 (4.4%)	ns
Therapeutic abortion	2 (5.9%)	0	ns
Voluntary interruption of pregnancy	1 (2.9%)	0	ns
Pre-term delivery	5 (14.7%)	6 (13.3%)	ns
Preterm rupture of membrane	3 (8.8%)	4 (8.9%)	ns
Intra-uterine growth restriction	1 (2.9%)	1 (2.2%)	ns
Average birth weight	2875 g (720-4234)	3140 (1880-4200)	ns
Low birth weight (<2500 g)	6 (17.6%)	5 (11.1%)	ns

Conclusions: In our case series no significant differences did occur in pregnancy outcome between BE and NE group, according to the most recent data published in literature. Additional data from larger numbers of pregnancy exposed to biological agents are required.

Disclosure of Interest: None declared

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SAT0157 MYCOBACTERIUM TUBERCULOSIS SPECIFIC RESPONSES FROM CD8+ AND CD4+ T CELLS IN PATIENTS WITH LATENT AND ACTIVE FORM OF TUBERCULOSIS

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Background: Testing the presence of latent or active tuberculosis using IGRA tests is necessary part of the diagnostic screening at risk individuals. QuantIFERON-TB Gold Plus (QFT-Plus) is a test for cell-mediated immune (CMI) responses to peptide antigens that simulate mycobacterial proteins. Peptide antigens in TB1 tube elicit CMI responses from CD4+ T-helper lymphocytes, in TB2 tube from CD8+ T-cytotoxic lymphocytes. Test is based on the ability of effector T lymphocytes to produce the cytokine interferon gamma (IFN-γ).

Objectives: To compare and evaluate levels of IFN-γ produced by CD4+ and CD8+ cells in TB1 and TB2 tubes.

Methods: It was studied 33 subjects with latent form of tuberculosis (LTBI) and 33 subjects with active TB. QFT-Plus was used to detect in vitro responses to peptide antigens associated with *Mycobacterium tuberculosis* infection (ELISA, QIAGEN). Results were obtained by calculation of INF-γ levels in Mitogen, TB antigen (TB1, TB2) and Negative control tubes using QFT analysis software.

Results: QFT-Plus positive results were observed in both groups of people. Increased levels of IFN-γ produced by CD4+ cells (TB1) has been detected in 21 subjects with LTBI (63.64%) and in all 33 subjects with active TB (100.0%). Increased levels of IFN-γ produced by CD8+ cells (TB2) has been detected in 27 people with LTBI (81.82%) and in all 33 people with active TB (100.0%). Joint increase levels of IFN-γ in the tubes TB1 and TB2 was observed in 16 individuals with LTBI (48.48%) and in all 33 individuals with active TB (100.0%). In the group of patients with a negative QFT-Plus it was not observed increased levels of IFN in tubes TB1 and TB2.

Conclusions: Our findings confirm specific CD4+ and CD8+ T cell response to mycobacterial protein antigens in individuals with LTBI and also in active TB subjects, in which INF-γ was frequently found. The immunological response represented by CD4+ and CD8+ T cells was not detected in subjects with QFT-Plus negative.

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SAT0158 EFFICACY OF SWITCHING FROM ETANERCEPT TO ADALIMUMAB IN RHEUMATOID ARTHRITIS AND PSORIATIC ARTHRITIS PATIENTS WHO EXPERIENCED A FIRST-LINE BIOLOGIC THERAPY FAILURE: THE FEARLESS STUDY

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Background: The strategy for the choice of the second biologic agent after the failure of the first TNF inhibitor (TNFi) is still an unclear aspect in the treatment of both rheumatoid arthritis (RA) and psoriatic arthritis (PsA). Switching between structurally different TNFis (from etanercept [ETN] to monoclonal antibody [mAb] or vice versa) has been proposed as a more effective procedure than switching among different mAbs, but to date no study has been specifically focused on exploring this topic.

Objectives: To evaluate the comparative 2-year retention rate and the 12-month efficacy of adalimumab (ADA) as second biologic agent in etanercept (ETN) non-responder RA and PsA patients in a multicentre retrospective study.

Methods: All RA and PsA patients from 11 Italian Rheumatology Units treated with ADA after a first-course ETN failure and with at least 12-month follow-up were retrospectively collected in a multicentre registry. Data analysis was limited to the period from January 2002 to May 2016. Two-year ADA retention rate was calculated by Kaplan-Meier method. 12-month ADA response was defined as achievement of disease activity score 28 calculated by using erythrocyte sedimentation (DAS28-ESR) <2.6 (remission) or >2.6 and <3.2 (low disease activity, LDA). Sub-analyses according to reason for ETN discontinuation and concomitant methotrexate in RA and PsA patients have been performed.

Results: The study population (219 patients) included 117 RA (female 85.5%, mean [± standard deviation, SD] age 53.2±13.5 years, mean [±SD] disease duration 10.1±7.7; positive rheumatoid factor 70.2%; positive anti-citrullinated peptide antibodies [ACPA] 59.6%; mean [±SD] baseline DAS28-ESR 4.97±1.3; MTX users 64.9%) and 102 PsA (female 63.7%; mean [±SD] age 51.7±10.6; mean [±SD] disease duration 7.1±5.1; mean [±SD] baseline DAS28-ESR 4.4±1.1; MTX users 50%). The 2-year retention rate was 48.2% in RA and 56.5% in PsA patients, irrespective of reason for ETN discontinuation. Similarly, concomitant MTX was not associated with an increased drug survival in both RA (p=0.09) and PsA (p=0.969) subgroup. 12-month clinical remission and LDA were achieved respectively in 27.3% and 23.9% RA patients, and 27.4% and 23.5% PsA patients.

Conclusions: In our large real-life cohort, the use of ADA in primary and secondary ETN failures was highly effective in both RA and PsA patients, with more than 50% of ADA treated patients achieving remission or LDA. Reasons for ETN discontinuation were not associated with different ADA clinical response, as well as concomitant MTX.

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SAT0159 IMPACT OF PARTICIPATION IN THE ADALIMUMAB PATIENT SUPPORT PROGRAM ON FUNCTIONAL AND CLINICAL OUTCOMES AMONG PATIENTS WITH RHEUMATOID ARTHRITIS: PASSION STUDY

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Background: Patients (pt) with Rheumatoid arthritis (RA) who are treated with adalimumab (ADA) are offered a Patient Support Program (PSP) with variety of services. To date, no prospective study has been conducted to analyze the acceptance and the impact of these PSPs on treatment effectiveness and pt satisfaction.

Objectives: The purpose of this study was to examine the effectiveness of ADA on rheumatoid arthritis (RA) treatment course in the context of PSP participation.

Methods: PASSION (NCT01383421) was a 78-week (wk) post-marketing observational study of pts with RA receiving ADA in routine clinical care. Pts from the EU, Israel, Mexico, Puerto Rico, and Australia with an insufficient response to ≥1 disease-modifying antirheumatic drug (DMARD) newly initiating ADA (1 prior