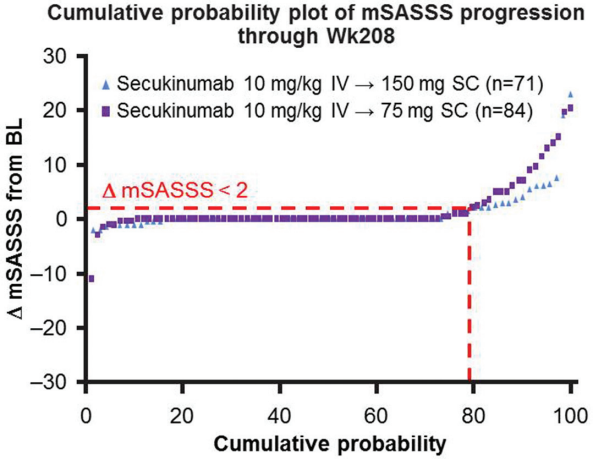
BL syndesmophytes or elevated BL hsCRP. Reductions from BL in the Berlin SI joint oedema and Berlin spine scores were seen with secukinumab 150 mg. Sustained efficacy in signs/symptoms was seen through 208 wks (Table). Exposure-adjusted incidence rates per 100 pt-yrs (total exposure [mean ±SD]=3.4 ±1.44 years) were: serious infections (1.0), IBD (0.7), uveitis (1.8) and malignant/unspecified tumours (0.5).

Abstract SAT0268 – Table 1. Efficacy at Wk208

	Secukinumab IV→150 mg (n=87)
mSASSS[a,b]	
BL (n=71 with X-rays at BL and Wk208)	8.8±16.23
Δ BL to Wk208	1.2±3.91
Δ BL to Wk104[c]/Δ Wk104 to 208[d]	0.5±1.69/0.8±3.34
MRI[a,b]	
Berlin SI joint total oedema score, Δ BL to Wk104/Δ BL to Wk208	–2.3±3.06[18]/–1.6±3.03[22]
Berlin spine score, Δ BL to Wk104/Δ BL to Wk208	–0.9±2.17[18]/–0.6±2.01[22]
Clinical efficacy	
ASAS20/40[e]	76.4/58.0
BASDAI,[f] Δ from BL	–3.3±0.23
ASDAS inactive disease[e]	27.6
BASFI/BASMI,[b] Δ from BL	–2.9±2.39 (80)/–0.5±1.12 (76)

n, no. of pts assessed; N, total no. of pts in extension trial
[a]Radiographs/MRIs taken at BL and Wk104 were re-read for pts completing Wk208 of treatment; [b]Mean±SD (n) for observed data; [c,d]Based on n=67 pts with X-rays at BL, Wk104 and Wk208 and BL mSASSS of [c]8.01±15.29 and [d]9.01±16.77, calculated from matched vertebral edges at BL and Wk104, and BL and Wk208, respectively; [e]% pts estimated using multiple imputation; [f]Least-squares mean±standard error for MMRM estimates



Conclusions: Secukinumab 150 mg showed numerically lower radiographic progression vs 75 mg at 4 years. Secukinumab also demonstrated sustained efficacy on signs and symptoms, and MRI outcomes and a consistent safety profile.[1]

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SAT0269

THE EFFECT OF BIOLOGIC DISEASE-MODIFYING ANTIRHEUMATIC DRUGS IN TARGETING DISEASE REMISSION IN AXIAL SPONDYLOARTHRITIS (AXSPA): A SYSTEMATIC LITERATURE REVIEW

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Background: The treat-to-target concept is currently recommended in axSpA management and remission is the main objective of treatment. Although consensual definitions of remission are lacking, most authors assume remission as a state of inactive disease or, alternatively, of low disease activity, as a near concept. In current practice, ASAS-Partial Remission (ASAS-PR) and ASDAS-Inactive Disease (ASDAS-ID) scores have gained wide acceptance as clinical remission-like definitions.

Objectives: In this review we assessed the efficacy of different biologic disease-modifying anti-rheumatic drugs (bDMARD) in achieving ASAS-PR or/and ASDAS-ID as remission-like primary outcomes. Data from randomised controlled trials (RCT) conducted in radiographic axSpA (r-axSpA) and non-radiographic axSpA (nr-axSpA) patients were included.

Methods: A systematic literature review was performed using the MEDLINE database (August 17 2017) with the filters "published in the last 10 years" and "humans". The PICO (P, population; I, intervention; C, comparison; O, outcome) concept was used to perform the analysis according to: Patients – adults (>18 years old) with r-axSpA or nr-axSpA; Intervention – any bDMARD regardless of formulation or duration; Comparison – placebo and/or any different drug; Outcomes: ASAS-PR and ASDAS-ID.

Results: After screening 557 references (after de-duplication), 7 RCTs fulfilled the inclusion criteria, all concerning tumour necrosis factor inhibitors (TNFi) bDMARDs – table 1. ASAS-PR was the most commonly used remission-like definition- in 6 of the 7 trials, 1 of those as a composed measure with a magnetic resonance score. Despite different baseline populations (including r-axSpA and nr-axSpA), all these trials provide evidence of TNFi efficacy in achieving remission. The proportion of patients achieving ASAS-PR and ASDAS-ID varied between 33%–61.9% and 27.3%–55%, respectively, with a minimum and maximum follow-up periods of 28 to 254 weeks for ASAS-PR and 24 weeks to 5 years for ASDAS-ID.

Abstract SAT0269 – Table 1. - bDMARD trials addressing ASAS-PR or ASDAS-ID as primary outcomes

Reference	Phenotype	Study design and duration	Drug (number of patients enrolled)	Primary Outcome	Results
Braun, 2008	r-axSpA	Extension 254 weeks	IFX/IFX *vs* PBO/IFX (38)	ASAS-PR	**34.2%**of patients achieved **ASAS-PR**
Sieper, 2012	r-axSpA and nr-axSpA	RCT 28 weeks	NPX +PBO (51) *vs* NPX +IFX (105)	ASAS-PR	**ASAS-PR in 61.9% NPX+IFX** *vs* 35.3% NPX+PBO (p<0.05)
Sieper, 2013	r-axSpA and nr-axSpA	Extension 52 weeks	NPX (40) *vs* no treatment (40) after partial remission under IFX+NPX or NPX+PBO	ASAS-PR	No statistically significant differences between the groups
Davis, 2008	r-axSpA	Extension 192 weeks	ETN/ETN (128) *vs* PBO/ETN (129)	ASAS-PR	**44%** of patients achieved **ASAS-PR**
Song, 2012	nr-axSpA	RCT (first part) 48 weeks	ETN (40) *vs* SSZ (36)	ASAS-PR plus MRI remission	**ASAS-PR+MRI remission in 33% ETN** vs 11% SSZ (p<0.05)
Sieper, 2011	r-axSpA	RCT and Extension 5 years	ADA/ADA *vs* PBO/ADA (311)	ASAS-PR and ASDAS-ID	**ASAS-PR in 45%** **ASDAS-ID in 55%**
van Heijde, 2014	r-axSpA	RCT (first part) 24 weeks	GOL (278) *vs* PBO (78)	ASDAS-ID	**ASDAS-ID in 27.3% GOL** *vs* 2.8% PBO (p<0.001)

Legend: - ADA: adalimumab; ASAS-PR: ASAS- Partial Remission; ASDAS-ID: ASDAS Inactive Disease; ETN: etanercept; GOL: golimumab; IFX: infliximab; MRI: magnetic resonance image; NPX: naproxen; nr-axSpA: non-radiographic axial spondyloarthritis; PBO: placebo; r-axSpA: radiographic spondyloarthritis; RCT: randomised controlled trial; SSZ: sulfasalazine, *vs – versus*.

Conclusions: Clinical trials addressing remission-like concepts as primary outcomes are scarce. ASAS-PR score was the most commonly used remission outcome. Depending on the studies, between one third to one half of patients treated with TNFi achieved ASAS-PR or ASDAS-ID. Considering nowadays aimed treatment targets, these data raise the unmet need for improved treatment options and strategies, that favour optimised remissions rates in axSpA patients.

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SAT0270 LOW INCIDENCE OF BOTH NEW-ONSET AND FLARES OF UVEITIS IN SECUKINUMAB-TREATED PATIENTS WITH ANKYLOSING SPONDYLITIS: CLINICAL TRIAL AND POST-MARKETING SAFETY ANALYSIS

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Background: Uveitis, a common extra-articular manifestation of SpA, has an estimated prevalence in patients (pts) with ankylosing spondylitis (AS) of 33.2%, which increases with disease duration and positive HLA-B27 status.[1] Uveitis occurs in 10%–50% of SpA pts.[1] The exposure-adjusted incidence rate [EAIR] of uveitis (combined new-onset and flares) reported in AS pts treated with TNF inhibitors is 2.6–3.5 per 100 patient-years (pt-yrs).[2–5]
Objectives: To assess the incidence of uveitis in secukinumab-treated AS pts in long-term pooled clinical data from three phase 3 trials (MEASURE 1–3 [NCT01358175, NCT01649375, NCT02008916]) and from post-marketing analyses.
Methods: Analysis included pooled pt-level data from all pts in MEASURE 1 who received any dose (≥1) of secukinumab up to the last pt attending Week 156 study visit, and up to visit Week 156 in MEASURE 2 and visit Week 104 in MEASURE 3 for each patient, respectively. Post-marketing data were from the most recent periodic safety surveillance report. Incidence of uveitis is reported as EAIR per 100 pt-yrs of secukinumab exposure.
Results: In the phase 3 AS clinical trials, 135 (17%) pts reported pre-existing (but not active or ongoing) uveitis at baseline and 589 (74.2%) pts were HLA-B27 positive. The EAIR for uveitis was 1.4 per 100 pt-yrs over the entire treatment period (n=794). Among all cases of uveitis (n=26), 14 (54%) were flares in pts with a history of uveitis at baseline (Table). The EAIR of uveitis in the post-marketing data (based on cumulative secukinumab exposure of 96 054 pt-yrs) was 0.03 per 100 pt-yrs.

Abstract SAT0270 – Table 1. Safety Analysis for Uveitis with Secukinumab in AS

Data from Clinical Studies	
Number of clinical studies/pts included	3/794
Uveitis cases reported, n (%)	
Total	26 (3.3%)
New onset cases	14 (1.8%)
Treatment discontinuation	2 (0.3%)
Treatment interruption	1 (0.1%)
EAIR (95% confidence interval) per 100 pt-yrs[a]	1.4 (0.9–2.0)
Post-Marketing Data[b]	
Cumulative estimated market experience (pt-treatment yrs)[c]	96 054
Cumulative number of cases reported	29
Crude incidence rate per 100 pt-yrs	0.03

[a]Rates are for uveitis MedDRA preferred term
[b]Data from the periodic safety update report (PSUR) dated 10th August 2017 – includes all indications
[c]Estimated based on cumulative worldwide sales volume and the average maintenance dose

Conclusions:
In secukinumab-treated pts with active AS, a low incidence of uveitis was observed, including new-onset cases and flares, in both clinical trials and post-marketing analyses.

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SAT0271 SECUKINUMAB, A FULLY HUMAN ANTI-INTERLEUKIN-17A MONOCLONAL ANTIBODY, EXHIBITS LOW IMMUNOGENICITY IN PATIENTS WITH PSORIATIC ARTHRITIS AND ANKYLOSING SPONDYLITIS DURING A 52-WEEK TREATMENT PERIOD

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Background: Secukinumab (SEC), a fully human monoclonal antibody (mAb) that selectively targets IL-17A, is highly efficacious for the treatment of psoriatic arthritis (PsA) and ankylosing spondylitis (AS). mAb therapies may be associated with immunogenicity (IG) and production of anti-drug antibodies (ADAs) that may cause adverse events (AEs), and affect drug pharmacokinetics (PK) and clinical response.

Abstract SAT0271 – Table 1. Overview of pts with TE-ADA[1]

PsA studies	Study	SEC dose	Prior biologics	ADA (titer)/ Neut-Ab	AE IG related	Impact on efficacy[2]	PK behaviour[3]
	F2306	PBO-75 mg	0	W24 (no titer)/Y	N	None	Normal
	F2312	PBO-150 mg	0	W52 (2.99)/N	N	None	Normal
	F2318	150 mg	Infliximab	W52 (2.14)/N	N	None	Normal
		150 mg	0	W24 (1.00)/N	N	None	Normal
		150 mg	0	W52 (2.59)/N	N	None	Normal
AS studies	F2305	10 mg/ kg– 150 mg	0	W52 (2.39)/N	N	None	Normal
		PBO-150 mg	0	W52 (10.61)/N	N	None	Normal
	F2310	PBO-75 mg	0	W52 (39.39)/N	N	None	Normal
	F2314	PBO-300 mg	0	W52 (1.02)/N	N	None	Normal
	F2320	150 mg	0	W16 (6.35)/N W52/ (2.96)/N	N	None None	Normal
		150 mg No Load	0	W16 (2.70)/N	N	None	Normal
		150 mg	0	W24/ (2.80)/N	N	None	Normal
		PBO– 150 mg	0	W52/ (2.89)/N	N	None	Normal