Conclusion: The gradient-boosting model previously identified predictors of abatacept retention from ACTION;² the addition of SHAP in this analysis has provided information on the importance and directionality of those predictors. The most important predictor of abatacept retention was no previous corticosteroid use, which was associated with lower retention. The models and predictors identified could be further refined by using additional datasets from clinical trials. Machine learning offers an innovative and complementary approach to biostatistics and could be used to identify treatment response predictors at an individual patient level, leading to a more personalised treatment approach.

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Figure 1. Overall variable importance in ACTION, using SHAP

Colours indicate the value of the variable: pink represents higher and blue represents lower. The bulges in the plot indicate the patients with that value; each dot represents a single patient. Higher SHAP values indicate a higher likelihood of retention. bDMARD=biologic DMARD; CCP=cyclic citrullinated peptide; SHAP=SHapley Additive exPlanations.

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AB0206

DESCRIPTION AND FOLLOW-UP OF RHEUMATOID ARTHRITIS PATIENTS WHO STOPPED B/TSDMARD THERAPY, STRATIFIED BY CESSATION REASON

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Background: Biologic or targeted synthetic disease modifying antirheumatic drugs (b/tsDMARD) may be stopped for several reasons such as non-response, adverse events, remission, or other reasons (e.g. major surgery). Understanding the reasons and consequences of b/tsDMARD therapy cessation may contribute towards therapy decision guidance. Moreover, identifying patient characteristics leading to the re-start of b/tsDMARD therapy may guide decision-making as to which patients should remain on continuous b/tsDMARD therapy versus who may potentially stop b/tsDMARD therapy.

Objectives: To describe and follow rheumatoid arthritis (RA) patients who stopped b/tsDMARD therapy, stratified by cessation reason.

Methods: We conducted a descriptive cohort study among adult RA patients in the longitudinal Swiss Clinical Quality Management in Rheumatic Diseases (SCQM) between 1997 and 2019. RA patients who stopped their first b/tsDMARD therapy were eligible, with therapy stop date defining cohort entry. We followed all eligible patients from cohort entry until b/tsDMARD re-start (the outcome) or censoring due to end of patient record. All analyses were carried out stratified by cessation reason (non-response, adverse events, remission, other reasons, unknown reasons). We described patient characteristics (demographics, lifestyle factors, clinical information, other medication use, relevant comorbidities) at cohort entry. Furthermore, we estimated Kaplan Meier curves to describe differences in cumulative incidences of b/tsDMARD re-start. Finally, we assessed patient characteristics at b/tsDMARD re-start and compared them with those at cohort entry.

Results: Among 2559 eligible RA patients, the majority stopped their b/tsDMARD due to non-response (982, 38%), followed by adverse events (475, 19%), other reasons (445, 17%), unknown reasons (444, 17%), and remission (213, 8%). Mean age at b/tsDMARD stop was around 56.2 years except in patients who stopped due to remission (mean age of 58.1 years). The majority of patients were women (78%), stopping due to an adverse event had the highest proportion of women (84%), stopping due to remission had the lowest proportion of women (70%). Compared to patients who stopped b/tsDMARD therapy due to non-response or adverse events, patients who stopped due to remission were generally more physically active, better educated, less likely to have a family history of rheumatic diseases, and had shorter median disease duration. A total of 2086 patients (82%) re-started b/tsDMARD therapy during follow-up. Of these, the majority did so after stopping due to non-response (94%), followed by adverse events (82%), unknown reasons (79%), other reasons (74%), and remission (47%). The median cumulative incidence of re-starting b/tsDMARD therapy was shortest after non-response (30 days), followed by unknown reasons (31 days), adverse events (94 days), other reasons (212 days), and remission (1597 days). The population who stopped b/tsDMARD therapy due to remission or other reasons yielded increased RA disease activity and an increase in proportions of women, cardiac diseases, degenerative joint disease, other auto-immune diseases, and of patients with family history of rheumatic diseases at the date of b/tsDMARD re-start. However, among patients who stopped b/tsDMARD therapy due to non-response or adverse events, patient characteristics at b/tsDMARD re-start were unchanged compared to those at b/tsDMARD stop.

Conclusion: Observed differences in patient characteristics at b/tsDMARD stop may yield insight into why the patient was not responding, had an adverse event, or achieved remission. Observed changes in patient characteristics from the date of b/tsDMARD stop to re-start identified which ones may lead to a worsening of RA activity in the absence of b/tsDMARD therapy.

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AB0207

ANALYSIS OF ABATACEPT TREATMENT RETENTION AND EFFICACY ACCORDING TO DISEASE DURATION AND TREATMENT LINE IN A REAL-WORLD SETTING

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Background: Longer disease duration and greater number of prior DMARDs have been associated with lower treatment efficacy in patients with RA.¹ Abatacept is a biologic (b)DMARD for treatment of moderate-to-severe RA and is available in SC formulation, which may offer convenience benefits with efficacy similar to IV administration.² ASCORE (Abatacept SubCutaneOus in Routine Clinical Practice; NCT02090556) was a 2-year, observational, prospective, multicentre study of SC abatacept for treatment of RA in routine clinical practice.³

Objectives: This *post hoc* analysis was conducted to determine if retention and efficacy of abatacept were impacted by disease duration and/or treatment line.

Methods: Eligible patients, aged ≥18 years, with active moderate-to-severe RA (ACR/EULAR 2010 criteria) who were IV abatacept-naïve and initiated SC abatacept 125mg once weekly, were enrolled into two cohorts: bDMARD-naïve patients and those with ≥1 prior bDMARD treatment failure. This *post hoc* analysis evaluated abatacept retention using Kaplan-Meier estimates, as well as disease activity scores (DAS28 [ESR]), CDAI and SDAI in patients with disease duration of ≤2, 3–5, 6–10 or >10 years, and in patients taking abatacept as first-line or ≥ second-line treatment.

Results: Table 1 shows baseline (BL) characteristics. Mean age increased with disease duration; other characteristics were comparable across groups. Retention proportions (95% CIs) at Month 24 were 0.50 (0.4, 0.5), 0.47 (0.4, 0.5), 0.51 (0.5, 0.5) and 0.46 (0.4, 0.5) in the ≤2, 3–5, 6–10 and >10 years' duration groups, respectively. Proportion of patients (95% CI) with ≤2 years' duration retaining treatment at Month 24 were 0.51 (0.4, 0.6) among those using abatacept as first-line treatment and 0.44 (0.3, 0.6) among those using abatacept as a ≥ second-line treatment (Figure 1). Proportions (95% CI) at Month 24 were 0.51 (0.5, 0.6), 0.57 (0.5, 0.6) and 0.52 (0.5, 0.6) in first-line patients and 0.43 (0.4, 0.5), 0.48 (0.4, 0.5) and 0.44 (0.4, 0.5) in ≥ second-line patients in the 3–5, 6–10 and >10 years' duration groups, respectively. Mean (SE) changes from BL in DAS28 (ESR) at Month 24 were –2.12 (0.205), –1.86 (0.151), –2.07 (0.140) and –2.05 (0.115) in the ≤2, 3–5, 6–10 and >10 years' duration groups, respectively; respective mean (SE) changes in CDAI were –18.74 (1.604), –15.60 (1.099), –18.50 (1.038) and –17.68 (0.850); and respective mean (SE) changes in SDAI were –19.10 (1.873), –15.72 (1.345), –19.54 (1.103) and –17.07 (0.939).

Conclusion: In this *post hoc* analysis of the real-world ASCORE trial, patients with RA receiving abatacept in clinical practice as first-line therapy had better retention versus those receiving it as a ≥ second-line treatment, regardless of disease duration at BL. Retention rates were similar across disease duration subgroups. Improvements in disease activity were seen in all duration subgroups, without consistently greater or lesser improvement seen with longer disease duration.

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Table 1. BL characteristics (n=2872)

	RA disease duration, years			
	≤2 (n=338)	3–5 (n=655)	6–10 (n=686)	>10 (n=1193)
Age, years				
n	338	655	686	1193
Mean (SD)	55.2 (12.8)	55.6 (12.7)	56.9 (13.0)	59.9 (12.2)
Weight, kg				
n	327	629	665	1150
Mean (SD)	75.3 (18.1)	76.4 (19.0)	74.7 (17.4)	72.9 (16.0)
DAS28 (ESR)				
n	247	439	441	743
Mean (SD)	5.2 (1.3)	4.9 (1.3)	5 (1.2)	5.1 (1.3)
DAS28 (CRP)				
n	267	460	467	799
Mean (SD)	4.7 (1.2)	4.6 (1.2)	4.7 (1.1)	4.7 (1.2)
CDAI				
n	269	477	474	805
Mean (SD)	26.9 (12.7)	25.3 (12.2)	26.8 (12.4)	26.6 (12.2)
SDAI				
n	255	448	445	749
Mean (SD)	28.3 (13.3)	26.8 (12.9)	27.9 (12.6)	28.0 (12.7)
RF status, n (%)				
RF+	159 (47.0)	342 (52.2)	345 (50.3)	597 (50.0)
RF–	103 (30.5)	152 (23.2)	158 (23.0)	215 (18.0)
Anti-CCP status, n (%)				
Anti-CCP+	165 (48.8)	332 (50.7)	333 (48.5)	516 (43.3)
Anti-CCP–	89 (26.3)	126 (19.2)	137 (20.0)	175 (14.7)

Patients with missing duration of disease are excluded. CCP=cyclic citrullinated peptide.

Figure 1. Treatment retention over 2 years among patients with RA with ≤2 years' disease duration

KM=Kaplan-Meier.

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AB0208

DO LOW CONCENTRATIONS OF CITRATE IN AN ADALIMUMAB FORMULATION IMPACT THE INCIDENCE AND/OR INTENSITY OF INJECTION SITE PAIN? DATA FROM PHASE I AND III STUDIES ASSESSING THE LOCAL TOLERANCE OF GP2017 (ADALIMUMAB BIOSIMILAR, SDZ-ADL) IN HEALTHY VOLUNTEERS, RHEUMATOID ARTHRITIS, AND PSORIASIS PATIENTS

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Background: Adalimumab (ADL) is typically self-administered every 2 weeks (W) as a subcutaneous (s.c.) injection by patients (pts) for diverse indications, including rheumatoid arthritis (RA), psoriatic arthritis (PsA), and psoriasis (PsO). Conflicting evaluations of local tolerance to formulations containing citrate buffer have created insecurities among health care professionals and pts.^{1,2}

Objectives: To evaluate local tolerance of SDZ-ADL (GP2017), a biosimilar ADL with low citrate concentration (1.2 mM),³ in 466 healthy volunteers (HV) and 408 pts (RA: 177 and PsO: 231 including PsA: 52) from four phase I pharmacokinetic (PK) and two phase III confirmatory studies.

Methods: HV evaluated their injection site pain (ISP) using a Visual Analogue Scale (VAS) of 0–100 mm. HV received a single 40 mg/0.8 mL s.c. injection and pts received SDZ-ADL every 2W during 48–51W duration of study. Injection site reactions (ISR) as well as adverse events (AEs) were assessed by investigators during the clinical studies. Details of study designs have been reported previously.^{4–7}

Results: Overall, 456 (97.9%) HV experienced no ISR. Ten HV experienced ISR. These were mostly of mild intensity; only 1 (0.2%) had an ISR of moderate intensity. 96.6% of HV experienced no pain (VAS score 0–4 mm)⁸ at 1-hour post-dose (Figure 1). In the phase III studies, a low number of ISR/ISP events were observed, which decreased during the course of study. Detailed results are provided in Table 1. No ISR/ISP led to treatment or study discontinuation in any study.

Conclusion: The proportion of HV and pts experiencing ISR and ISP after administration of SDZ-ADL was low, with no events leading to treatment or study discontinuation. These results call into question the clinical impact of citrate and its concentration in ADL formulations on the incidence and intensity of ISP.

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Figure 1. Proportion of HV with ISP in phase I PK studies

Table 1. ISP and ISR results from phase I PK and phase III confirmatory studies

Phase I PK studies					
Study	101 (N=73)	102 (N=108)	103 (N=178)	104 (N=107)	Pooled studies (N=466)
VAS scores (mm) at 1-hour post-dose					
Mean (SD)	0.89 (2.07)	0.07 (0.52)	1.03 (1.71)	1.03 (2.49)	0.79 (1.84)
Median	0	0	1	0	0
ISR scores at 1-hour post-dose, n (%)					
None	73 (100)	106 (98.2)	178 (100)	99 (92.5)	456 (97.9)
Mild	0 (0)	1 (0.9)	0 (0)	8 (7.5)	9 (1.9)
Moderate	0 (0)	1 (0.9)	0 (0)	0 (0)	1 (0.2)
Phase III confirmatory studies					
	ADACCESS^{5*} (PsO and PsA pts) W0–17 (N=231)	ADMYRA^{6*} (RA pts) W0–51 (N=168; including pts re-randomised to continue SDZ-ADL after W17)		W0–24 (N=177)	W0–48 (N=177; all pts continued SDZ-ADL after W24)
Dosage	Induction 80 mg W0, then 40 mg EoW s.c.	40 mg EoW s.c.		40 mg EoW s.c.	40 mg EoW s.c.
Study duration, W	17	51		24	48
AEs - ISR, n (%)	15 (6.5), 34	9 (5.4), 26		7 (4.0), 11	7 (4.0), 12
Mild	14 (6.1), 30	9 (5.4), 26		7 (4.0), 11	7 (4.0), 12
Moderate	1 (0.4), 4	0		0	0
AEs - ISP (reported as ISR), n (%)	3 (1.3)	1 (0.6)		2 (1.1)	2 (1.1)

*ADACCESS and ADMYRA were switch studies, therefore, only pts exposed to SDZ-ADL throughout the study period are included here. EoW, every other week, N, number of HV or pts

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