Supplementary Appendix

Real-World Effectiveness and Safety of SDZ ETN, an Etanercept Biosimilar, in Patients with Rheumatic Diseases: Final Results from Multi-Country COMPACT Study

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Table S1 Detailed inclusion/exclusion criteria

Inclusion criteria

1. Adult patients (aged ≥ 18 years) at the time of enrolment
2. Patients with
    a. RA, axSpA or PsA, in clinical remission or low disease activity, under treatment with reference ETN or other biosimilar ETN (iETN) and switched to SDZ ETN prior to study enrolment or
    b. RA, axSpA or PsA who received previous treatment with another anti-TNF agent or any other biologic treatment or with targeted synthetic DMARD (JAKi) according to the respective SmPC, and who had been switched to SDZ ETN prior to study enrolment or
    c. RA or PsA considered uncontrolled (i.e. non-responsive) after at least 3 months of treatment with conventional synthetic DMARDs (or in case of RA only also ± other DMARDs) who had been initiated on SDZ ETN prior to study enrolment. For patients with axSpA, after at least two NSAIDs over 4 weeks of treatment or
    d. recent diagnosis of RA considered suitable for treatment initiation with a biologic (first-line treatment with SDZ ETN) and who had been started on treatment with SDZ ETN prior to study enrolment

    Enrolled patients who did not meet inclusion criterion 2 were followed in the study and treated as group E. These patients were assessed for safety only
3. All patients found eligible for participation in the study must have started treatment with SDZ ETN (according to the prescribing recommendations in each particular country) before an ICF was signed and enrolment in the study took place

4. For France only: For patients under judicial protection (i.e. legally incompetent, or not able to read, or mentally ill or unable to express consent), a specific ICF had to be signed by a respective legal guardian or curator
Exclusion criteria 1. Any contraindications to ETN according to the prescribing recommendations in each country 2. Known hypersensitivity to ETN

axSpA axial spondyloarthritis, *DMARD* disease-modifying anti-rheumatic drug, *ETN* etanercept, *ICF* informed consent form, *iETN* initial ETN, *JAKi* Janus kinase inhibitor, *NSAID* nonsteroidal anti-inflammatory drug, *PsA* psoriatic arthritis, *RA* rheumatoid arthritis, *SDZ ETN* Sandoz etanercept, *SmPC* summary of product characteristics, *TNF* tumour necrosis factor

Table S2 Prior and concomitant medications

	RA ***N* = 844** ***n* (%)**	**PsA** ***N* = 288** ***n* (%)**	**axSpA** ***N* = 334** ***n* (%)**	**Total** ***N* = 1466** ***n* (%)**
Immunosuppressants	651 (77.1)	190 (66.0)	97 (29.0)	938 (64.0)
Methotrexate	439 (52.0)	122 (42.4)	45 (13.5)	606 (41.3)
Leflunomide	110 (13.0)	25 (8.7)	1 (0.3)	136 (9.3)
Anti-inflammatory and anti-rheumatic products	249 (29.5)	91 (31.6)	181 (54.2)	521 (35.5)
Ibuprofen	67 (7.9)	15 (5.2)	40 (12.0)	122 (8.3)
Diclofenac	40 (4.7)	14 (4.9)	40 (12.0)	94 (6.4)
Systemic corticosteroids	312 (37.0)	57 (19.8)	17 (5.1)	386 (26.3)
Drugs for acid related disorders	201 (23.8)	44 (15.3)	54 (16.2)	299 (20.4)
Analgesics	152 (18.0)	43 (14.9)	64 (19.2)	259 (17.7)
Agents acting on the renin-angiotensin system	162 (19.2)	44 (15.3)	31 (9.3)	237 (16.2)
Lipid-modifying agents	98 (11.6)	20 (6.9)	17 (5.1)	135 (9.2)
Thyroid therapy	91 (10.8)	21 (7.3)	15 (4.5)	127 (8.7)
Beta-blocking agents	88 (10.4)	18 (6.3)	18 (5.4)	124 (8.5)
Antithrombotic agents	77 (9.1)	10 (3.5)	16 (4.8)	103 (7.0)
Calcium channel blockers	64 (7.6)	19 (6.6)	7 (2.1)	90 (6.1)
Drugs used in diabetes	45 (5.3)	17 (5.9)	10 (3.0)	72 (4.9)
Diuretics	44 (5.2)	10 (3.5)	12 (3.6)	66 (4.5)
Drugs for obstructive airway diseases	43 (5.1)	8 (2.8)	10 (3.0)	61 (4.2)

Drugs for treatment of bone diseases	49 (5.8)	5 (1.7)	5 (1.5)	59 (4.0)

axSpA axial spondyloarthritis, *N* total number of patients in the group, *n* number of patients with available assessments, *PsA* psoriatic arthritis, *RA* rheumatoid arthritis

Table S3 Disease activity scores in patients who continued or discontinued the treatment at month 12

Mean ± SD (*n*)	**Group A**		**Group B**		**Group C**		**Group D**		**Total**	
	Day 1	**Month 12**	**Day 1**	**Month 12**	**Day 1**	**Month 12**	**Day 1**	**Month 12**	**Day 1**	**Month 12**
DAS28-ESR score in patients with RA										
	N = 295		*N* = 88		*N* = 451		*N* = 10		*N* = 844	
Continuation group	2.4 ± 1.1 (235)	2.4 ± 1.3 (123)	3.4 ± 1.2 (55)	2.7 ± 1.1 (41)	3.1 ± 1.5 (309)	2.6 ± 1.2 (197)	3.5 ± 1.0 (5)	4.3 ± 2.5 (2)	2.9 ± 1.4 (604)	2.6 ± 1.2 (363)
Discontinuation group (overall)	3.3 ± 1.3 (23)	3.5 ± 1.3 (11)	4.1 ± 1.5 (15)	2.7 ± 0.6 (6)	3.8 ± 1.5 (83)	3.7 ± 1.6 (41)	4.2 ± 1.7 (3)	0	3.7 ± 1.5 (124)	3.5 ± 1.5 (58)
Discontinuation due to lack of efficacy	3.8 ± 1.5 (11)	4.4 ± 2.0 (3)	4.0 ± 1.5 (8)	2.9 ± 0.8 (3)	3.8 ± 1.5 (42)	3.8 ± 1.8 (19)	3.3 ± 0.9 (2)	0	3.8 ± 1.5 (63)	3.7 ± 1.7 (25)
DAS28-ESR score in patients with PsA										
	N = 117		*N* = 36		*N* = 135		*N* = 0		*N* = 288	
Continuation group	2.0 ± 1.0 (72)	2.5 ± 1.8 (30)	2.8 ± 1.6 (24)	2.1 ± 0.8 (10)	2.7 ± 1.6 (91)	2.2 ± 1.3 (53)	–	–	2.5 ± 1.4 (187)	2.3 ± 1.5 (93)
Discontinuation group (overall)	3.0 ± 1.1 (8)	4.2 ± 2.6 (2)	3.5 ± 1.7 (6)	4.1 ± 2.7 (3)	3.5 ± 1.6 (25)	3.2 ± 1.3 (7)	–	–	3.4 ± 1.5 (39)	3.6 ± 1.8 (12)
Discontinuation due to lack of efficacy	3.3 ± 1.2 (6)	6.0 ± 0.0 (1)	4.5 ± 1.0 (4)	5.7 ± 0.5 (2)	3.7 ±1.5 (14)	3.7 ± 1.6 (4)	–	–	3.7 ± 1.3 (24)	4.6 ± 1.6 (7)
ASDAS score in patients with axSpA										
	N = 160		*N* = 47		*N* = 127		*N* = 0		*N* = 334	
Continuation group	1.6 ± 0.6 (73)	1.7 ± 0.9 (36)	1.8 ± 0.8 (15)	1.9 ± 0.6 (8)	2.1 ± 0.9 (45)	1.8 ± 0.9 (22)	–	–	1.8 ± 0.8 (133)	1.8 ± 0.8 (66)
Discontinuation group (overall)	1.9 ± 0.5 (4)	2.5 ± 1.2 (3)	1.9 ± 1.1 (3)	0	2.6 ± 0.9 (14)	4.2 ± 0.0 (1)	–	–	2.4 ± 0.9 (21)	2.9 ± 1.3 (4)
Discontinuation due to lack of efficacy	1.8 ± 0.0 (1)	1.5 ± 0.0 (1)	1.0 ± 0.0 (1)	0	3.1 ± 1.1 (5)	0	–	–	2.6 ± 1.2 (7)	1.5 ± 0.0 (1)

BASDAI score in patients with axSpA										
Continuation group	2.0 ± 1.6 (131)	2.0 ± 1.8 (77)	2.6 ± 2.4 (33)	2.2 ± 1.6 (19)	3.3 ± 2.3 (91)	2.6 ± 2.1 (73)	–	–	2.5 ± 2.1 (255)	2.3 ± 1.9 (169)
Discontinuation group (overall)	3.1 ± 2.4 (9)	2.2 ± 1.5 (6)	3.7 ± 2.1 (11)	4.5 ± 0.5 (4)	5.6 ± 2.3 (29)	4.3 ± 2.7 (13)	–	–	4.7 ± 2.5 (49)	3.8 ± 2.4 (23)
Discontinuation due to lack of efficacy	4.0 ± 2.6 (3)	2.0±1.9 (3)	4.1±4.0 (3)	5.1 (1)	5.8 ± 2.3 (12)	3.1±3.0 (5)	–	–	5.2 ± 2.6 (18)	2.9 ± 2.5 (9)

Continuation group includes patients who continued SDZ ETN treatment after month 12; discontinuation group (overall) includes patients who discontinued SDZ ETN treatment before or at month 12; discontinuation due to lack of efficacy includes patients who discontinued SDZ ETN treatment before or at month 12 due to lack of efficacy

The total group includes patients who were either treated with reference ETN or biosimilar ETN (initial ETN; iETN) other than SDZ ETN and switched to SDZ ETN (group A), or patients who received non–ETN targeted therapies and switched to SDZ ETN (group B) or were biologic-naïve (group C) or DMARD-naïve patients who started SDZ ETN as the first biologic therapy (group D). There were no patients with PsA or axSpA who were DMARD-naïve and started SDZ ETN as the first biologic therapy (group D, *N* = 0)

ASDAS ankylosing spondylitis disease activity score, *axSpA* axial spondyloarthritis, *BASDAI* Bath Ankylosing Spondylitis Disease Activity Index, *DAS28-ESR* Disease Activity Score 28-joint count Erythrocyte Sedimentation Rate, *N* total number of patients in the group, *n* number of patients with available assessments, *PsA* psoriatic arthritis, *RA* rheumatoid arthritis, *SDZ ETN* Sandoz etanercept, *SD* standard deviation

Table S4 PROs and QoL in patients with RA

Mean ± SD (*n*)	**Group A (*N* = 295)**		**Group B (*N* = 88)**		**Group C (*N* = 451)**		**Group D (*N* = 10)**		**Total* (*N* = 844)**	
	Day 1	**Month 12**	**Day 1**	**Month 12**	**Day 1**	**Month 12**	**Day 1**	**Month 12**	**Day 1**	**Month 12**
Physical Function										
HAQ-DI	0.8 ± 0.7 (221)	0.7 ± 0.7 (103)	1.2 ± 0.6 (78)	1.1 ± 0.6 (45)	0.9 ± 0.7 (361)	0.9 ± 0.7 (207)	1.3 ± 0.6 (9)	1.3 ± 0.4 (5)	0.9 ± 0.7 (669)	0.8 ± 0.7 (360)
SF-12 Physical Health	44.8 ± 8.2 (106)	44.5 ± 7.6 (44)	40.4 ± 7.4 (44)	39.3 ± 7.8 (21)	41.4 ± 9.0 (246)	42.8 ± 8.6 (125)	36.6 ± 6.0 (7)	38.0 ± 2.5 (4)	42.1 ± 8.7 (403)	42.7 ± 8.3 (194)
Health related QoL										
SF-12 Mental Health	47.7 ± 7.9 (106)	48.2 ± 8.0 (44)	43.6 ± 6.7 (44)	41.9 ± 9.0 (21)	45.6 ± 8.9 (246)	47.5 ± 8.4 (125)	41.7 ±6.6 (7)	35.1 ± 9.7 (4)	45.9 ± 8.5 (403)	46.8 ± 8.7 (194)
EQ-5D VAS	67.2 ± 25.1 (142)	69.2 ± 20.1 (57)	63.4 ± 19.1 (47)	56.7 ± 22.9 (23)	64.3 ± 21.2 (284)	64.5 ± 23.5 (145)	55.6 ± 18.8 (8)	41.8 ± 7.4 (3)	64.9 ± 22.2 (481)	64.6 ± 22.8 (228)
Fatigue										
FACIT-Fatigue	37.0 ± 8.3 (125)	37.0 ± 8.5 (47)	33.0 ± 9.1 (48)	31.0 ± 11.8 (24)	34.0 ± 10.0 (272)	35.0 ± 9.2 (143)	35.0 ± 10.2 (8)	21.0 ± 11.1 (3)	35.0 ± 9.5 (453)	35.0 ± 9.6 (217)
Fatigue VAS	28.7 ± 23.1 (42)	28.4 ± 26.2 (14)	46.6 ± 27.7 (12)	44.0 ± 26.1 (5)	36.9 ± 27.9 (69)	32.8 ± 24.3 (15)	–	–	35.1 ± 26.7 (123)	32.6 ± 25.1 (34)
Pain										
BPI – Interference Score	1.9 ± 2.1 (81)	2.0 ± 1.9 (31)	3.4 ± 2.5 (31)	3.0 ± 2.2 (11)	2.9 ± 2.5 (171)	2.8 ± 2.2 (75)	5.0 ± 0.6 (3)	7.1 ± 0.9 (2)	2.7 ± 2.4 (286)	2.7 ± 2.2 (119)
Pain VAS score	2.3 ± 2.2 (84)	2.7 ± 1.9 (32)	3.4 ± 2.3 (31)	3.1 ± 1.9 (12)	3.1 ± 2.2 (169)	3.0 ± 2.2 (76)	5.7 ± 2.2 (3)	5.4 ± 0.2 (2)	2.9 ± 2.2 (287)	3.0 ± 2.1 (122)
Overall pain: Experience of pain[#] (Yes), *n* (%)	44 (53.7)	16 (51.6)	18 (58.1)	3 (30.0)	102 (60.0)	38 (53.5)	2 (66.7)	1 (100.0)	166 (58.0)	58 (51.3)

*The total group includes patients with RA who were either treated with reference ETN or biosimilar ETN (initial ETN; iETN) other than SDZ ETN and switched to SDZ ETN (group A), or patients who received non-ETN targeted therapies and switched to SDZ ETN (group B), or biologic-naïve (group C) or DMARD-naïve patients who started SDZ ETN as the first biologic therapy (group D); [#]Pain experienced during current day by visit and group

BPI basic pain inventory, *EQ-5D* EuroQoL 5-dimensions, *FACIT* Functional Assessment of Chronic Illness Therapy, *HAQ-DI* Health Assessment Questionnaire-Disability Index, *n* number of patients available for assessments, *QoL* quality of life, *PRO* patient-reported outcome, *RA* rheumatoid arthritis, *SDZ ETN* Sandoz etanercept, *SD* standard deviation, *SF-12* Short Form Health Survey 12-item, *VAS* visual analogue scale

Table S5 PROs and QoL in patients with PsA

Mean ± SD (*n*)	**Group A (*N* = 117)**		**Group B (*N* = 36)**		**Group C (*N* = 135)**		**Total* (*N* = 288)**	
	Day 1	**Month 12**	**Day 1**	**Month 12**	**Day 1**	**Month 12**	**Day 1**	**Month 12**
Physical Function								
HAQ-DI	0.5 ± 0.7 (76)	0.7 ± 0.7 (30)	1.0 ± 0.7 (27)	0.8 ± 0.6 (13)	0.7 ± 0.6 (105)	0.5 ± 0.7 (65)	0.7 ± 0.7 (208)	0.6 ± 0.7 (108)
SF-12 Physical Health	45.1 ± 8.5 (41)	43.9 ± 9.4 (17)	41.7 ± 9.0 (14)	40.2 ± 8.2 (7)	43.4 ± 8.4 (66)	45.5 ± 9.3 (32)	43.8 ± 8.5 (121)	44.3 ± 9.2 (56)
Health related QoL								
SF-12 Mental Health	46.4 ± 8.7 (41)	47.1 ± 8.3 (17)	44.2 ± 6.4 (14)	42.0 ± 5.7 (7)	48.2 ± 8.7 (66)	48.8 ± 10.0 (32)	47.1 ± 8.5 (121)	47.4 ± 9.2 (56)
EQ-5D VAS	65.8 ± 24.3 (54)	64.2 ± 19.3 (22)	57.2 ± 21.2 (13)	63.0 ± 15.9 (7)	59.2 ± 24.2 (77)	74.1 ± 18.4 (38)	61.5 ± 24.1 (144)	69.7 ± 18.9 (67)
Fatigue								
FACIT-Fatigue	36.0 ± 8.4 (43)	35.0 ± 10.4 (22)	32.0 ± 10.0 (14)	32.0 ± 5.1 (6)	34.0 ± 9.9 (72)	36.0 ± 9.8 (32)	35.0 ± 9.4 (129)	36 ± 9.7 (60)
Fatigue VAS	27.3 ± 22.8 (11)	43.3 ± 45.1 (3)	48.4 ± 20.9 (9)	34.2 ± 19.1 (6)	34.7 ± 31.7 (23)	33.3 ± 24.9 (4)	35.7 ± 28.1 (43)	36.0 ± 25.8 (13)
Pain								
BPI – Interference Score	2.6 ± 2.4 (37)	2.9 ± 2.8 (13)	2.7 ± 2.1 (12)	3.7 ± 3.2 (6)	2.7 ± 2.3 (42)	2.1 ± 2.5 (21)	2.6 ± 2.3 (91)	2.6 ± 2.7 (40)
Pain VAS score								
Overall pain: Experience of pain[#] (Yes), *n* (%)	22 (57.9)	7 (53.8)	9 (75.0)	4 (80.0)	22 (52.4)	9 (40.9)	53 (57.6)	20 (50.0)

*The total group includes patients with PsA who were either treated with reference ETN or biosimilar ETN (initial ETN; iETN) other than SDZ ETN and switched to SDZ ETN (group A), or patients who received non-ETN targeted therapies and switched to SDZ ETN (group B) or were biologic-naïve (group C). There were no patients with PsA who were DMARD-naïve and started SDZ ETN as the first biologic therapy (group D, *N* = 0)
[#]Pain experienced during current day by visit and group

BPI basic pain inventory, *EQ-5D* EuroQoL 5-dimensions, *FACIT* Functional Assessment of Chronic Illness Therapy, *HAQ-DI* Health Assessment Questionnaire-Disability Index, *n* number of patients available for assessments, *QoL* quality of life, *PRO* patient-reported outcome, *PsA* psoriatic arthritis, *SDZ ETN* Sandoz etanercept, *SD* standard deviation, *SF-12* Short Form Health Survey 12-item, *VAS* visual analogue scale

Table S6 PROs and QoL in patients with axSpA

Mean ± SD (*n*)	**Group A (*N* = 160)**		**Group B (*N* = 47)**		**Group C (*N* = 127)**		**Total* (*N* = 334)**	
	Day 1	**Month 12**	**Day 1**	**Month 12**	**Day 1**	**Month 12**	**Day 1**	**Month 12**
Physical Function								
HAQ-DI	0.5 ± 0.6 (102)	0.4 ± 0.4 (54)	0.9 ± 0.6 (22)	0.8 ± 0.6 (9)	0.8 ± 0.6 (96)	0.6 ± 0.6 (63)	0.7 ± 0.6 (220)	0.5 ± 0.6 (126)
SF-12 Physical Health	46.8 ± 7.8 (73)	46.8 ± 8.0 (40)	42.1 ± 9.2 (16)	39.0 ± 10.2 (6)	40.2 ± 8.3 (62)	44.8 ± 8.7 (41)	43.6 ± 8.7 (151)	45.4 ± 8.6 (87)
Health related QoL								
SF-12 Mental Health	49.2 ± 7.7 (73)	49.2 ± 8.3 (40)	46.5 ± 7.7 (16)	43.9 ± 8.2 (6)	44.3 ± 8.9 (62)	48.0 ± 8.2 (41)	46.9 ± 8.5 (151)	48.3 ± 8.2 (87)
EQ-5D VAS	68.8 ± 21.9 (81)	73.0 ± 19.4 (37)	55.3 ± 27.0 (19)	74.9 ± 17.6 (6)	60.2 ± 21.6 (76)	62.6 ± 23.4 (51)	63.6 ± 22.8 (176)	67.5 ± 22.0 (94)
Fatigue								
FACIT-Fatigue	37.0 ± 7.7 (79)	38.0 ± 7.3 (41)	35.0 ± 7.7 (20)	29.0 ± 14.4 (5)	31.0 ± 9.8 (70)	35.0 ± 7.9 (44)	34.0 ± 9.1 (169)	36.0 ± 8.3 (90)
Fatigue VAS	21.4 ± 19.3 (28)	29.0 ± 25.1 (5)	28.0 ± 27.8 (5)	10.0 ± 0.0 (1)	34.3 ± 32.4 (18)	28.3 ± 35.0 (8)	26.6 ± 25.6 (51)	27.2 ± 29.6 (14)
Pain								
BPI – Interference Score	2.0 ± 2.1 (61)	1.9 ± 1.9 (31)	3.1 ± 2.3 (15)	3.8 ± 3.1 (4)	4.5 ± 2.7 (45)	2.7 ± 2.4 (23)	3.1 ± 2.6 (121)	2.4 ± 2.2 (58)
Pain VAS score								
Overall pain: Experience of pain[#] (Yes), *n* (%)	30 (49.2)	12 (40.0)	7 (46.7)	3 (100.0)	30 (69.8)	13 (61.9)	67 (56.3)	28 (51.9)

*The total group includes patients with axSpA who were either treated with reference ETN or biosimilar ETN (initial ETN; iETN) other than SDZ ETN and switched to SDZ ETN (group A), or patients who received non-ETN targeted therapies and switched to SDZ ETN (group B) or were biologic-naïve (group C). There were no patients with axSpA who were DMARD-naïve and started SDZ ETN as the first biologic therapy (group D, *N* = 0)

[#]Pain experienced during current day by visit and group

axSpA axial spondyloarthritis, *BPI* basic pain inventory, *EQ-5D* EuroQoL 5-dimensions, *FACIT* Functional Assessment of Chronic Illness Therapy, *HAQ-DI* Health Assessment Questionnaire-Disability Index, *n* number of patients available for assessments, *QoL* quality of life, *PRO* patient-reported outcome, *SDZ ETN* Sandoz etanercept, *SD* standard deviation, *SF-12* Short Form Health Survey 12-item, *VAS* visual analogue scale

Table S7 Details of institutional review boards and ethics committees

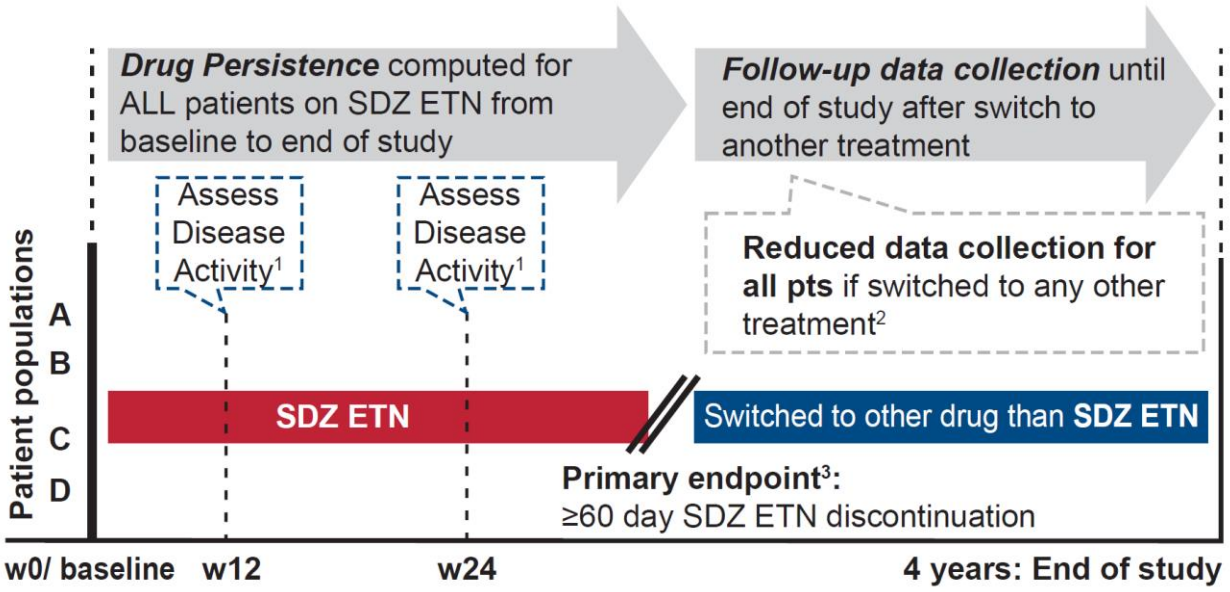
Country	IRB/EC Name/Address	Central/ Regional/ Local
Austria	Ethikkommission der Medizinischen Universität Wien Borschkegasse 8b/E06 1090, Wien	Central
Canada	Advarra 372 Hollandview Trail, suite 300 Aurora ON, L4G 0A5	Central
Switzerland	Ethikkommission Nordwest- und Zentralschweiz (EKNZ) Hebelstrasse 53 4056, Basel	Central
Germany	EthikKommission der Bayerischen Landesärztekammer Mühlbaurstrasse16 81677, München	Local
Germany	EthikKommission des Fachbereichs Medizin der Justus-Liebig-Universität Gießen Klinikstrasse 29 35392, Gießen	Local
Germany	Ärztekammer Berlin Friedrichstrasse 16 10969, Berlin	Local
Germany	EthikKommission der Ärztekammer Nordrhein Tersteegenstrasse 9 40474, Düsseldorf	Local
Germany	Ethikkommission der Sächsischen Landesärztekammer Schützenhöhe 16 01099, Dresden	Local
Germany	EthikKommission der Ärztekammer Sachsen-Anhalt Am Kirchtor 9 06108, Halle	Local
Germany	Ethikkommission der Landesärztekammer Thüringen Im Semmicht 33 07751, Jena	Local
Germany	Ethikkommission bei der Ärztekammer Niedersachsen Karl-Wiechert-Allee 18-22 30625, Hannover	Local
Germany	Ethikkommission der medizinischen Fakultät Heidelberg Alte Glockengießerei 11/1 69115, Heidelberg	Local
Germany	EthikKommission bei der Landesärztekammer Baden-Württemberg Liebknechtstrasse 33 70565, Stuttgart	Primary
Germany	Medizinische Ethikkommission an der Julius-Maximilians-Universität Würzburg Josef-Schneider-Strasse 4, C15 97080, Würzburg	Local
France	Comités de protection des personnes (CPP) Est IV 1 Place de l'hôpital 67000, Strasbourg	Central

Italy	Comitato etico per la Sperimentazione Clinica (CESC) delle Province di Verona e Rovigo Servizio di Farmacia dell'Ospedale Borgo Trento Piazzale Stefani 1 37126, Verona	Local
Italy	Comitato Etico Spedali Civili di Brescia Piazzale Spedali Civili 1 25123, Brescia	Local
Italy	Comitato Etico Catania 1 c/o Azienda Ospedaliero Universitaria Via Santa Sofia 78 95123, Catania	Local
Italy	Comitato Etico della provincia di Bergamo c/o ASST Papa Giovanni XXIII Piazza Organizzazione Mondiale della Sanità (OMS) 1 24127, Bergamo	Local
Italy	Comitato Etico Palermo 1 A.O.U. Paolo Giaccone Via del Vespro 129 90127, Palermo	Local
Italy	Comitato Etico Messina Azienda Ospedaliera Universitaria Gaetano Martino Via Consolare Valeria 1 98125, Gazzi (ME)	Central
Italy	Comitato Etico Lazio 1 Azienda Ospedaliera San Camillo Forlanini Circonvallazione Gianicolense 87 00152, Roma	Local
Italy	Comitato Etico Unico Regionale (CEUR) IRCCS Centro di Riferimento Oncologico - CRO Via Gallina 2 33081, Aviano	Local
Poland	Komisja Bioetyczna przy Uniwersytecie Medycznym we Wrocławiu ul. J. Mikulicza-Radeckiego 4a 50-367, Wrocław	Central
Spain	Comité de Etica de la Investigación con Medicamentos (CEIm) Regional de la Comunidad de Madrid C/ Aduana, 29 - 3ª planta 28013, Madrid	Central
Spain	Extremadura: MIGUEL ANGEL MARTIN DE LA NAVA <miguelangel.martind@salud-juntaex.es>	Regional
Spain	Galicia: ceimg@sergas.es	Regional
Spain	Murcia: CARLOS CHILLERON, MARIA ANGELES <mariaa.carlos@carm.es>	Regional
Spain	Cataluña: Jambrina Albiach, Anna Maria <amjambrina@gencat.cat>	Regional
Spain	Andalucía: Secretaría Técnica CCEIBA <cceiba.csalud@juntadeandalucia.es>	Regional
Spain	Castilla la Mancha: Epidemiologia (Sanidad - JCCM) <ve@jccm.es>	Regional
Spain	Castilla y León: Maria del Carmen Mendizabal de la Cruz mcarmen.mendizabal@jcyl.es	Regional
Spain	Comité de Ética de la Investigación con medicamentos de Cáceres Hospital San Pedro de Alcántara Avda. Pablo Naranjo 10003, Cáceres	Local

Spain	Instituto Murciano De Investigación Biosanitaria Clínico Universitario Virgen de la Arrixaca - 3ª Planta C/ Campo 12 30120 - El Palmar - Murcia	Local
Spain	Comité de Ética de la Investigación con medicamentos (CEIm) Área de Salud de Badajoz Av. de Huelva 8 06005, Badajoz	Local
Spain	Comité Ético de Investigación Clínica del Parc de Salut Mar Hospital del Mar C/ del Doctor Aiguader 88 08003, Barcelona	Local
Spain	Comité de Ética de la Investigación con medicamentos (CEIm) del Hospital Universitari Vall d'Hebron Passeig de la Vall d'Hebron 119 08035, Barcelona	Local
Spain	Comité de Ética de Investigación con medicamentos (CEIm) del Parc Taulí Parc Tauli 1, Edifici Santa Fe Sabadell, Cataluña, 8208	Local
Spain	Comité de Ética de Investigación con medicamentos (CEIm) Girona Institut d'Investigació Biomèdica de Girona Dr. Josep Trueta (IDIBGI) C/Dr. Castany, Parc Hospitalari Martí i Julià - Edifici M2 17190, Salt (Girona)	Local
Spain	Comité de Ética de Investigación con medicamentos (CEIm) del Hospital Universitari MútuaTerrassa Pl/ Doctor Robert 5, planta -1 08221, Terrassa, Barcelona	Local
Spain	Comité de Ética de Investigación con medicamentos (CEIm) Fundació Hospital Asil de Granollers Avinguda Francesc Ribas 08402, Granollers, Barcelona	Local
Spain	Comité de Ética de Investigación con medicamentos (CEIm) Hospital Clinic de Barcelona C. de Villarroel 170 08036, Barcelona	Local
Spain	Comité de Ética de Investigación con medicamentos (CEIm) Hospital Virgen de la Macarena Av. Dr. Fedriani 3 41009, Sevilla	Local
Spain	Comité Ético de Investigación Clínica Hospital Virgen de las Nieves Avenida de las Fuerzas Armadas 2 18014, Granada	Local
Spain	Comité de Ética de la Investigación de Córdoba Hospital Reina Sofia Avda. Menéndez Pidal 14004, Córdoba	Local
Spain	Comité de Ética de Investigación con medicamentos (CEIm) de la GAI de Guadalajara Hospital Universitario de Guadalajara C. Donante de Sangre 19002, Guadalajara	Local
Spain	Comité de Ética de Investigación con medicamentos (CEIm) Alcázar de San Juan Hospital General Universitario de Ciudad Real (HGUCR) C. Obispo Rafael Torija 13005, Ciudad Real	Local

Spain	Comité de Ética de Investigación con medicamentos (CEIm) del Hospital General Universitario de Ciudad Real C. Obispo Rafael Torija 13005, Ciudad Real	Local
Spain	Comité de Ética de Investigación con medicamentos (CEIm) de las Áreas de Salud de León y El Bierzo Hospital de Leon Calle Altos de Nava 24008, León	Local
United Kingdom	East Midlands - Nottingham 2 Research Ethics Committee The Old Chapel Royal Standard Place Nottingham, NG1 6FS	Central

Figure S1 Study Design

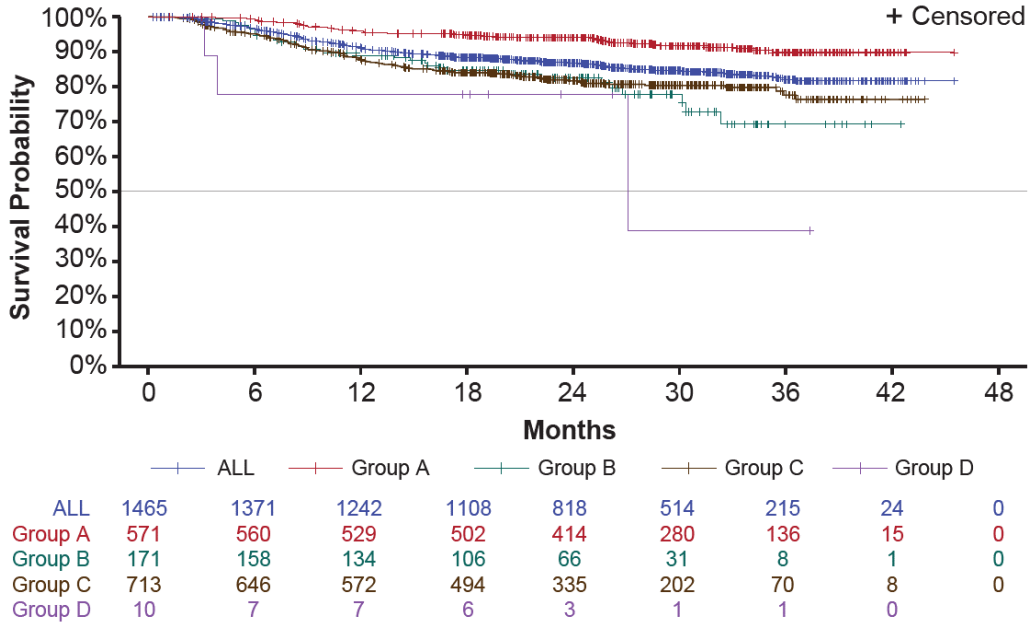


[1]Disease Assessment via Disease Activity Score, Ankylosing Spondylitis Disease Activity Score and Bath Ankylosing Spondylosis Disease Activity Index. [2]Full data collection follow-up according to the same extend as in core protocol; reduced data collection; follow-up with only limited data (which drug, when, Safety). [3]Primary endpoint: Drug persistence as time from enrolment until discontinuation of SDZ ETN ≥ 60 days

pts patients, *SDZ ETN* Sandoz etanercept, *w* week

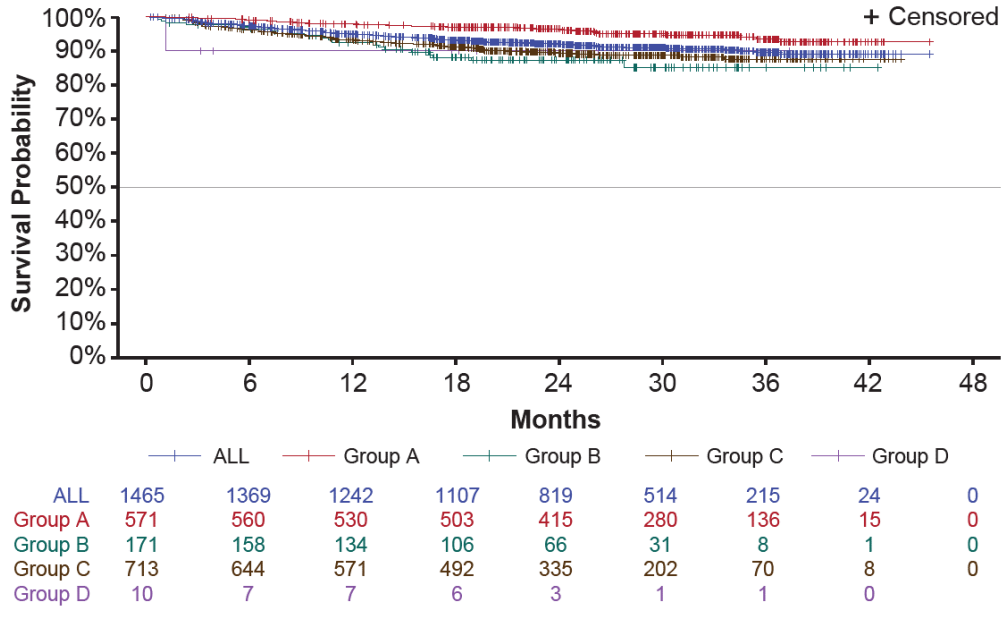
Figure S2 Kaplan–Meier plot for drug persistence survival analysis based on reason for discontinuation from SDZ ETN treatment start (overall population)

a.



ALL	1465	1371	1242	1108	818	514	215	24	0
Group A	571	560	529	502	414	280	136	15	0
Group B	171	158	134	106	66	31	8	1	0
Group C	713	646	572	494	335	202	70	8	0
Group D	10	7	7	6	3	1	1	0	

b.



ALL	1465	1369	1242	1107	819	514	215	24	0
Group A	571	560	530	503	415	280	136	15	0
Group B	171	158	134	106	66	31	8	1	0
Group C	713	644	571	492	335	202	70	8	0
Group D	10	7	7	6	3	1	1	0	

a Discontinuation due to lack of efficacy; **b** discontinuation due to AEs

AE adverse event, *SDZ ETN* Sandoz etanercept