

Supplementary Materials

Table S1. Adverse event distribution by bDMARDs according to MedDRA® System Organ Class and Preferred Term classification

Adverse event, <i>n</i> (%)	ABT	ADA	CZP	ETN	GOL	IFX	SEC	TCZ	UST	Total
Infections and infestations	9 (9.5)	9 (3.4)	2 (6.5)	10 (2.9)	10 (11.0)	2 (1.9)	3 (3.8)	2 (2.0)		47 (4.1)
Bronchitis	1 (1.1)	1 (0.4)	1 (3.2)		3 (3.3)		1 (1.3)			7 (0.6)
Cystitis		1 (0.4)								1 (0.1)
Ear infection				1 (0.3)						1 (0.1)
Eye infection					1 (1.1)					1 (0.1)
Herpes simplex		1 (0.4)				1 (0.9)				2 (0.2)
Herpes zoster	1 (1.1)			2 (0.6)		1 (0.9)	1 (1.3)			5 (0.4)
Infection				1 (0.3)						1 (0.1)
Influenza	3 (3.2)	1 (0.4)		3 (0.9)	2 (2.2)					9 (0.8)
Localized infection					1 (1.1)					1 (0.1)
Lung infection		1 (0.4)								1 (0.1)
Measles	1 (1.1)									1 (0.1)
Molluscum contagiosum	1 (1.1)									1 (0.1)
Oral candidiasis		1 (0.4)								1 (0.1)
Oral fungal infection				1 (0.3)						1 (0.1)
Oral herpes	1 (1.1)									1 (0.1)
Oral infection					1 (1.1)					1 (0.1)
Osteomyelitis								1 (1.0)		1 (0.1)
Otitis media					1 (1.1)					1 (0.1)
Papilloma viral infection				1 (0.3)						1 (0.1)
Paronychia								1 (1.0)		1 (0.1)
Pneumonia			1 (3.2)							1 (0.1)
Progressive multifocal leukoencephalopathy		1 (0.4)								1 (0.1)
Rhinitis	1 (1.1)									1 (0.1)
Tonsillitis				1 (0.3)						1 (0.1)
Tooth abscess		2 (0.8)					1 (1.3)			3 (0.3)
Tooth infection					1 (1.1)					1 (0.1)
Musculoskeletal and connective tissue disorders	4 (4.2)	6 (2.3)	3 (9.7)	11 (3.2)	5 (5.5)		2 (2.6)	1 (1.0)	6 (17.1)	38 (3.3)
Arthralgia	1 (1.1)	1 (0.4)	1 (3.2)							3 (0.3)
Arthritis	1 (1.1)	4 (1.5)		9 (0.9)	3 (3.3)		2 (2.6)	1 (1.0)	3 (8.6)	23 (2.0)
Dactylitis				1 (0.3)					1 (2.9)	2 (0.2)
Enthesopathy					1 (1.1)					1 (0.1)
Flank pain	1 (1.1)									1 (0.1)
Joint swelling	1 (1.1)									1 (0.1)
Pain in extremity		1 (0.4)								1 (0.1)
Psoriatic arthropathy			1 (3.2)						2 (5.7)	3 (0.3)
Rheumatoid arthritis			1 (3.2)	1 (0.3)						2 (0.2)
Sacroiliitis					1 (1.1)					1 (0.1)
Skin and subcutaneous tissue disorders	6 (6.3)	1 (0.4)	1 (3.2)	10 (2.9)	3 (3.3)	8 (7.5)	1 (1.3)	3 (3.0)	2 (5.7)	35 (3.0)
Butterfly rash						1 (0.9)				1 (0.1)
Eczema				1 (0.3)						1 (0.1)
Hyperhidrosis						1 (0.9)				1 (0.1)
Mechanical urticaria				1 (0.3)						1 (0.1)
Nail disorder					1 (1.1)					1 (0.1)
Nodular rash	1 (1.1)									1 (0.1)
Palmar erythema					1 (1.1)					1 (0.1)
Pruritus			1 (3.2)	2 (0.6)		2 (1.9)				5 (0.4)
Psoriasis				2 (0.6)	1 (1.1)		1 (1.3)			4 (0.3)
Rash	2 (2.1)	1 (0.4)		2 (0.6)		2 (1.9)		2 (2.0)	1 (2.9)	10 (0.9)
Rash pruritic	1 (1.1)			2 (0.6)					1 (2.9)	4 (0.3)
Skin exfoliation	1 (1.1)									1 (0.1)
Umbilical hemorrhage	1 (1.1)									1 (0.1)
Urticaria						2 (1.9)		1 (1.0)		3 (0.3)
General disorders and administration site conditions		3 (1.1)		11 (3.2)		5 (4.7)		5 (5.0)		24 (2.1)
Administration site pruritus								1 (1.0)		1 (0.1)

Asthenia		1 (0.4)		1 (0.9)		2 (0.2)	
Chest pain		1 (0.4)	2 (0.6)			3 (0.3)	
Condition aggravated			4 (1.2)		1 (1.0)	5 (0.4)	
Influenza like illness					1 (1.0)	1 (0.1)	
Injection site hypersensitivity				1 (0.9)		1 (0.1)	
Injection site pain			1 (0.3)		1 (1.0)	2 (0.2)	
Injection site urticaria	1 (0.4)		3 (0.9)	1 (0.9)		5 (0.4)	
Malaise				1 (0.9)		1 (0.1)	
Pyrexia			1 (0.3)	1 (0.9)		2 (0.2)	
Swelling					1 (1.0)	1 (0.1)	
Respiratory, thoracic and mediastinal disorders	1 (1.1)	2 (0.8)	3 (0.9)	4 (3.7)	4 (4.0)	14 (1.2)	
Acute respiratory failure		1 (0.4)				1 (0.1)	
Asthma			1 (0.3)			1 (0.1)	
Bronchospasm			1 (0.3)			1 (0.1)	
Chronic obstructive pulmonary disease	1 (1.1)					1 (0.1)	
Cough				1 (0.9)	1 (1.0)	2 (0.2)	
Dysphonia					1 (1.0)	1 (0.1)	
Dyspnoea			1 (0.3)	2 (1.9)		3 (0.3)	
Laryngeal pain					1 (1.0)	1 (0.1)	
Oropharyngeal pain					1 (1.0)	1 (0.1)	
Pulmonary mass		1 (0.4)				1 (0.1)	
Tonsillar hypertrophy				1 (0.9)		1 (0.1)	
Blood and lymphatic system disorders		3 (1.1)	4 (1.2)	2 (1.9)	4 (4.0)	13 (1.1)	
Leukopenia					1 (1.0)	1 (0.1)	
Lymphocytosis		1 (0.4)	2 (0.6)	1 (0.9)	1 (1.0)	5 (0.4)	
Neutropenia		2 (0.8)	2 (0.6)	1 (0.9)	2 (2.0)	7 (0.6)	
Investigations		7 (2.7)		2 (1.9)		9 (0.8)	
Antinuclear antibody positive		1 (0.4)		1 (0.9)		2 (0.2)	
DNA antibody positive				1 (0.9)		1 (0.1)	
Histone antibody positive		1 (0.4)				1 (0.1)	
Protein C increased		1 (0.4)				1 (0.1)	
Red blood cell sedimentation rate increased		3 (1.1)				3 (0.3)	
Rheumatoid factor increased		1 (0.4)				1 (0.1)	
Nervous system disorders		5 (1.9)	1 (0.3)	2 (1.9)		8 (0.7)	
Crawling sensation		1 (0.4)				1 (0.1)	
Demyelination			1 (0.3)			1 (0.1)	
Dizziness		2 (0.8)		1 (0.9)		3 (0.3)	
Headache				1 (0.9)		1 (0.1)	
Paresthesia		1 (0.4)				1 (0.1)	
Syncope		1 (0.4)				1 (0.1)	
Eye disorders	1 (1.1)		5 (1.5)	1 (0.9)		7 (0.6)	
Blurred vision	1 (1.1)					1 (0.1)	
Glaucoma			1 (0.3)			1 (0.1)	
Uveitis			4 (1.2)	1 (0.9)		5 (0.4)	
Gastrointestinal disorders	1 (1.1)	1 (0.4)		1 (1.1)	1 (0.9)	1 (1.0)	5 (0.4)
Abdominal distension	1 (1.1)						1 (0.1)
Crohn's disease				1 (1.1)			1 (0.1)
Nausea		1 (0.4)		1 (0.9)			2 (0.2)
Oral pain					1 (1.0)		1 (0.1)
Hepatobiliary disorders					1 (1.0)	2 (5.7)	4 (0.3)
Hepatic steatosis						1 (2.9)	1 (0.1)
Hypertransaminasemia					1 (1.0)	1 (2.9)	3 (0.3)
Reproductive system and breast disorders			2 (0.6)				2 (0.2)
Benign prostatic hyperplasia			1 (0.3)				1 (0.1)
Cervix disorder			1 (0.3)				1 (0.1)
Neoplasms benign, malignant and unspecified		1 (0.4)		1 (1.1)			2 (0.2)
Basal cell carcinoma				1 (1.1)			1 (0.1)
Breast cancer		1 (0.4)					1 (0.1)
Vascular disorders			1 (3.2)	1 (0.3)			2 (0.2)

Flushing		1 (3.2)	1 (0.3)	2 (0.2)
Ear and labyrinth disorders	1 (1.1)	1 (0.4)		2 (0.2)
Tinnitus	1 (1.1)			1 (0.1)
Vertigo		1 (0.4)		1 (0.1)
Cardiac disorders		1 (0.4)	1 (0.3)	2 (0.2)
Atrial fibrillation			1 (0.3)	1 (0.1)
Myocardial infarction		1 (0.4)		1 (0.1)
Injury, poisoning and procedural complications			1 (0.9)	1 (0.1)
Infusion related reaction			1 (1.9)	1 (0.1)
Psychiatric disorders		1 (0.4)		1 (0.1)
Confusional state		1 (0.4)		1 (0.1)

Abbreviations: ABT = abatacept, ADA = adalimumab, CZP = certolizumab pegol, ETN = etanercept, GOL = golimumab, IFX = infliximab, SEC = secukinumab, TCZ = tocilizumab, and UST = ustekinumab. For nakinra only one case of hypertransaminasemia was registered (not reported). Percentages were calculated on the total of patients treated with each reference bDMARD. Bold indicates values for MedDRA® System Organ Class classification.