ONLINE SUPPLEMENTAL MATERIALS

Long-term safety and effectiveness of canakinumab therapy in patients with cryopyrin-associated periodic syndrome: results from the β-Confident Registry

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Table S1 Treatment history at enrolment into registry

	FCAS (N=42)	MWS (N=169)	NOMID (N=32)	All CAPS (N=243)	Other* (N=42)	All (N=285)
IL-1 inhibitor including canakinumab (clinical trial or marketed)	35 (83.3)	152 (89.9)	29 (90.6)	216 (88.9)	36 (85.7)	252 (88.4)
IL-1 inhibitor including canakinumab in a clinical trial	28 (66.7)	112 (66.3)	25 (78.1)	165 (67.9)	24 (57.1)	189 (66.3)
Canakinumab prior to enrolment	34 (81.0)	134 (79.3)	21 (65.6)	189 (77.8)	27 (64.3)	216 (75.8)
Canakinumab in a clinical trial	24 (57.1)	71 (42.0)	9 (28.1)	104 (42.8)	0	104 (36.5)
Marketed canakinumab only	10 (23.8)	63 (37.3)	12 (37.5)	85 (35.0)	27 (64.3)	112 (39.3)
Other IL-1 inhibitor	16 (38.1)	77 (45.6)	24 (75.0)	117 (48.1)	24 (57.1)	141 (49.5)
Other auto-inflammatory disease medication (excluding IL-1 inhibitor)	19 (45.2)	70 (41.4)	19 (59.4)	108 (44.4)	29 (69.0)	137 (48.1)
Corticosteroids	7 (16.7)	42 (24.9)	15 (46.9)	64 (26.3)	24 (57.1)	88 (30.9)
NSAIDs	14 (33.3)	49 (29.0)	10 (31.3)	73 (30.0)	14 (33.3)	87 (30.5)
csDMARD	1 (2.4)	15 (8.9)	8 (25.0)	24 (9.9)	14 (33.3)	38 (13.3)
Anti-TNF agent	0	6 (3.6)	5 (15.6)	11 (4.5)	9 (21.4)	20 (7.0)

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IL-6 inhibitor	0	1 (0.6)	0	1 (0.4)	1 (2.4)	2 (0.7)
Other	3 (7.1)	9 (5.3)	1 (3.1)	13 (5.3)	12 (28.6)	25 (8.8)

Values are n (%) unless stated otherwise

*Other includes atypical CAPS (n=18) and non-CAPS diagnoses (n=24); non-CAPS diagnoses include systemic juvenile idiopathic arthritis, unspecified autoinflammatory syndromes, familial Mediterranean fever, mevalonate kinase deficiency, adult-onset Still's disease, tumour necrosis factor receptor-associated periodic syndrome, Erdheim–Chester disease, Blau syndrome and granulomatosis with polyangiitis.

Canakinumab prior to enrolment refers to canakinumab use at least 28 days before baseline (date of inform consent); other inflammatory inhibitors includes antihistamine, colchicine, dapsone, gold, mesalazine, mycophenolate, tegeline and thalidomide.

csDMARD, conventional synthetic disease modifying rheumatic drugs encompassing methotrexate, azathioprine, cyclophosphamide, and mycophenolic acid/mycophenolate mofetil.

CAPS, cryopyrin-associated periodic syndromes; csDMARD, conventional synthetic disease-modifying antirheumatic drug; FCAS, familial cold autoinflammatory syndrome; IL, interleukin; MWS, Muckle–Wells syndrome; NOMID, neonatal-onset multisystem inflammatory disease; NSAID, non-steroidal anti-inflammatory drug; TNF, tumour necrosis factor.

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Table S2 Baseline canakinumab dose by phenotype

Dose categories (mg/kg)	FCAS (N=42)	MWS (N=169)	NOMID (N=32)	All CAPS (N=243)	Other* (N=42)	All (N=285)
<2 mg/kg	16 (38.1)	43 (25.4)	2 (6.3)	61 (25.1)	9 (21.4)	70 (24.6)
2–<4 mg/kg	22 (52.4)	83 (49.1)	18 (56.3)	123 (50.6)	24 (57.1)	147 (51.6)
4–<8 mg/kg	0	21 (12.4)	8 (25.0)	29 (11.9)	4 (9.5)	33 (11.6)
>=8 mg/kg	0	1 (0.6)	3 (9.4)	4 (1.6)	0	4 (1.4)

Values are n (%) unless stated otherwise

*Other includes atypical CAPS (n=18) and non-CAPS diagnoses (n=24); non-CAPS diagnoses include systemic juvenile idiopathic arthritis, unspecified autoinflammatory syndromes, familial Mediterranean fever, mevalonate kinase deficiency, adult-onset Still's disease, tumour necrosis factor receptor-associated periodic syndrome, Erdheim–Chester disease, Blau syndrome and granulomatosis with polyangiitis.

CAPS, cryopyrin-associated periodic syndromes; FCAS, familial cold autoinflammatory syndrome; MWS, Muckle–Wells syndrome; NOMID, neonatal-onset multisystem inflammatory disease.

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Table S3 Changes in audiogram, ophthalmological assessments, and brain MRI from baseline to last available assessment

	FCAS (N=42)	MWS (N=169)	NOMID (N=32)	All CAPS (N=243)	Other* (N=42)	All (N=285)
Abnormal audiogram, % (m/n)						
Baseline	14.3 (3/21)	57.0 (69/121)	66.7 (14/21)	52.8 (86/163)	50.0 (2/4)	52.7 (88/167)
Last available assessment	0.0 (0/11)	57.4 (66/115)	66.7 (14/21)	54.4 (80/147)	25.0 (2/8)	52.9 (82/155)
Abnormal ophthalmologic assessment, % (m/n)						
Baseline	11.1 (2/18)	24.7 (20/81)	50.0 (10/20)	26.9 (32/119)	25.0 (2/8)	26.8 (34/127)
Last available assessment	0.0 (0/2)	15.9 (14/88)	57.1 (12/21)	23.4 (26/111)	15.4 (2/13)	22.6 (28/124)
Abnormal brain MRI assessment, % (m/n)						
Baseline	20.0 (3/15)	14.0 (6/43)	37.5 (6/16)	20.3 (15/74)	0 (0/2)	19.7 (15/76)
Last available assessment	0.0 (0/6)	11.4 (4/35)	35.7 (5/14)	16.4 (9/55)	0 (0/6)	14.8 (9/61)

% values are calculated based on the number of patients with available data at the time of assessment (m/n)

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*Other includes atypical CAPS (n=18) and non-CAPS diagnoses (n=24); non-CAPS diagnoses include systemic juvenile idiopathic arthritis, unspecified autoinflammatory syndromes, familial Mediterranean fever, mevalonate kinase deficiency, adult-onset Still's disease, tumour necrosis factor receptor-associated periodic syndrome, Erdheim–Chester disease, Blau syndrome and granulomatosis with polyangiitis.

CAPS, cryopyrin-associated periodic syndromes; FCAS, familial cold autoinflammatory syndrome; m, number of patients who reported disease characteristic; MRI, magnetic resonance imaging; MWS, Muckle–Wells syndrome; n, number of patients with available data in subgroup; NOMID, neonatal-onset multisystem inflammatory disease.

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Table S4 Delay in sexual maturation and neurocognitive function at baseline and last available assessment

	FCAS (N=8)	MWS (N=44)	NOMID (N=14)	All CAPS (N=66)	Other* (N=17)	All (N=83)
Delay in sexual maturation, % (m/n)						
Baseline	0.0 (0/6)	2.9 (1/34)	12.5 (1/8)	4.2 (2/48)	16.7 (2/12)	6.7 (4/60)
Last available assessment	0.0 (0/5)	0.0 (0/35)	0.0 (0/9)	0.0 (0/49)	14.3 (2/14)	3.2 (2/63)
Delay in neurocognitive function, % (m/n)						
Baseline	0.0 (0/7)	2.4 (1/41)	45.5 (5/11)	10.2 (6/59)	0.0 (0/15)	8.1 (6/74)
Last available assessment	0.0 (0/6)	5.1 (2/39)	30.8 (4/13)	10.3 (6/58)	0.0 (0/16)	8.1 (6/74)

% values are calculated based on the number of patients with available data at the time of assessment (m/n); data were collected only from patients aged ≥6 and <18 years

m = number of patients who reported disease characteristic; n = number of patients with available data in subgroup

*Other includes atypical CAPS (n=18) and non-CAPS diagnoses (n=24); non-CAPS diagnoses include systemic juvenile idiopathic arthritis, unspecified autoinflammatory syndromes, familial Mediterranean fever, mevalonate kinase deficiency, adult-onset Still's disease, tumour necrosis factor-receptor associated periodic syndrome, Erdheim-Chester disease, Blau syndrome, and granulomatosis with polyangiitis.

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CAPS, cryopyrin-associated periodic syndromes; FCAS, familial cold autoinflammatory syndrome;

MWS, Muckle–Wells syndrome; NOMID, neonatal-onset multisystem inflammatory disease.

Table S5 Adverse events by phenotypes

SOC, Preferred term, n (IR/ 100 PY) (95% CI)	FCAS N= 42	MWS N=169	NOMID N= 32	All CAPS N=243	Other* N= 42	ALL N=285
All events	114 (73.1) [60.3, 87.8]	681 (105.0) [97.2, 113.2]	119 (104.6) [86.6, 125.2]	914 (99.5) [93.2, 106.2]	200 (143.1) [124.0-164.4]	1114 (105.3) [99.2, 111.6]
Infections and Infestations	54 (34.6) [26.0, 45.2]	244 (37.6) [33.0, 42.6]	45 (39.6) [28.8, 52.9]	343 (37.3) [33.5, 41.5]	59 (42.2) [32.1, 54.5]	402 (38.0) [34.4- 41.9]
Nasopharyngitis	13 (8.3) [4.4, 14.3]	69 (10.6) [8.3, 13.5]	11 (9.7) [4.8, 17.3]	93 (10.1) [8.2, 12.4]	7 (5.0) [2.0, 10.3]	100 (9.4) [7.7, 11.5]
Gastroenteritis	6 (3.8) [1.4, 8.4]	13 (2.0) [1.1, 3.4]	1 (0.9) [0.0, 4.9]	20 (2.2) [1.3, 3.4]	6 (4.3) [1.6, 9.3]	26 (2.5) [1.6, 3.6]
Influenza	6 (3.8) [1.4, 8.4]	8 (1.2) [0.5, 2.4]	2 (1.8) [0.2, 6.3]	16 (1.7) [1.0, 2.8]	4 (2.9) [0.8, 7.3]	20 (1.9) [1.2, 2.9]
Tonsillitis	2 (1.3) [0.2, 4.6]	11 (1.7) [0.8, 3.0]	1 (0.9) [0.0, 4.9]	14 (1.5) [0.8, 2.6]	5 (3.6) [1.3, 8.3]	19 (1.8) [1.2, 2.8]
Urinary tract infection	3 (1.9) [0.4, 5.6]	13 (2.0) [1.1, 3.4]	2 (1.8) [0.2, 6.3]	18 (2.0) [1.2, 3.1]	0 [0.0, 2.7]	18 (1.7) [1.0, 2.7]
Pharyngitis	0 [0.0, 2.4]	12 (1.8) [1.0, 3.2]	2 (1.8) [0.2, 6.3]	14 (1.5) [0.8, 2.6]	2 (1.4) [0.2, 5.2]	16 (1.5) [0.9, 2.5]
Bronchitis	1 (0.6) [0.0, 3.6]	8 (1.2) [0.5, 2.4]	2 (1.8) [0.2, 6.3]	11 (1.2) [0.6, 2.1]	3 (2.1) [0.4, 6.3]	14 (1.3) [0.7, 2.2]
Lower respiratory tract infection	5 (3.2) [1.0, 7.5]	4 (0.6) [0.2, 1.6]	5 (4.4) [1.4,10.3]	14 (1.5) [0.8, 2.6]	0 [0.0, 2.7]	14 (1.3) [0.7, 2.2]
Viral infection	2 (1.3) [0.2, 4.6]	6 (0.9) [0.3, 2.0]	1 (0.9) [0.0, 4.9]	9 (1.0) [0.4, 1.9]	2 (1.4) [0.2, 5.2]	11 (1.0) [0.5, 1.9]
Ear infection	3 (1.9) [0.4, 5.6]	5 (0.8) [0.3, 1.8]	0 [0.0, 3.2]	8 (0.9) [0.4, 1.7]	1 (0.7) [0.0, 4.0]	9 (0.9) [0.4, 1.6]
Oral herpes	5 (3.2) [1.0, 7.5]	3 (0.5) [0.1, 1.4]	0 [0.0, 3.2]	8 (0.9) [0.4, 1.7]	0 [0.0, 2.7]	8 (0.8) [0.3, 1.5]
Rhinitis	0 [0.0, 2.4]	5 (0.8) [0.3, 1.8]	2 (1.8) [0.2, 6.3]	7 (0.8) [0.3, 1.6]	1 (0.7) [0.0, 4.0]	8 (0.8) [0.3, 1.5]

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SOC, Preferred term, n (IR/ 100 PY) (95% CI)	FCAS N= 42	MWS N=169	NOMID N= 32	All CAPS N=243	Other* N= 42	ALL N=285
Pneumonia	0 [0.0, 2.4]	5 (0.8) [0.3, 1.8]	0 [0.0, 3.2]	5 (0.5) [0.2, 1.3]	2 (1.4) [0.2, 5.2]	7 (0.7) [0.3, 1.4]
Sinusitis	0 [0.0, 2.4]	3 (0.5) [0.1, 1.4]	1 (0.9) [0.0, 5.0]	4 (0.4) [0.1, 1.1]	3 (2.2) [0.4, 6.3]	7 (0.7) [0.3, 1.4]
Herpes zoster	0 [0.0, 2.4]	5 (0.8) [0.3, 1.8]	0 [0.0, 3.2]	5 (0.5) [0.2, 1.3]	1 (0.7) [0.0, 4.0]	6 (0.6) [0.2, 1.2]
Upper respiratory tract infection	0 [0.0, 2.4]	3 (0.5) [0.1, 1.4]	0 [0.0, 3.2]	3 (0.3) [0.1, 1.0]	3 (2.1) [0.4, 6.3]	6 (0.6) [0.2, 1.2]
Laryngitis	1 (0.6) [0.0, 3.6]	4 (0.6) [0.2, 1.6]	0 [0.0, 3.2]	5 (0.5) [0.2, 1.3]	0 [0.0, 2.7]	5 (0.5) [0.2, 1.1]
Respiratory tract infection	0 [0.0, 2.4]	2 (0.3) [0.0, 1.1]	1 (0.9) [0.0, 4.9]	3 (0.3) [0.1, 1.0]	2 (1.4) [0.2, 5.2]	5 (0.5) [0.2, 1.1]
Viral upper respiratory tract infection	1 (0.6) [0.0, 3.6]	2 (0.3) [0.0, 1.1]	2 (1.8) [0.2, 6.3]	5 (0.5) [0.2, 1.3]	0 [0.0, 2.7]	5 (0.5) [0.2, 1.1]
Folliculitis	0 [0.0, 2.4]	4 (0.6) [0.2, 1.6]	0 [0.0, 3.2]	4 (0.4) [0.1, 1.1]	0 [0.0, 2.7]	4 (0.4) [0.1, 1.0]
Cellulitis	0 [0.0, 2.4]	2 (0.3) [0.0, 1.1]	1 (0.9) [0.0, 4.9]	3 (0.3) [0.1, 1.0]	0 [0.0, 2.7]	3 (0.3) [0.1, 0.8]
Conjunctivitis	0 [0.0, 2.4]	2 (0.3) [0.0, 1.1]	1 (0.9) [0.0, 4.9]	3 (0.3) [0.1, 1.0]	0 [0.0, 2.7]	3 (0.3) [0.1, 0.8]
Cystitis	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	2 (1.8) [0.2, 6.3]	3 (0.3) [0.1, 1.0]	0 [0.0, 2.7]	3 (0.3) [0.1, 0.8]
Herpes virus infection	0 [0.0, 2.4]	2 (0.3) [0.0, 1.1]	1 (0.9) [0.2, 4.9]	3 (0.3) [0.1, 1.0]	0 [0.0, 2.7]	3 (0.3) [0.1, 0.8]
Hordeolum	0 [0.0, 2.4]	3 (0.5) [0.1, 1.4]	0 [0.0, 3.2]	3 (0.3) [0.1, 1.0]	0 [0.0, 2.7]	3 (0.3) [0.1, 0.8]
Onychomycosis	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	2 (1.4) [0.2, 5.2]	3 (0.3) [0.1, 0.8]
Otitis externa	0 [0.0, 2.4]	3 (0.5) [0.1, 1.4]	0 [0.0, 3.2]	3 (0.3) [0.1, 1.0]	0 [0.0, 2.7]	3 (0.3) [0.1, 0.8]

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SOC, Preferred term, n (IR/ 100 PY) (95% CI)	FCAS N= 42	MWS N=169	NOMID N= 32	All CAPS N=243	Other* N= 42	ALL N=285
Pharyngitis streptococcal	0 [0.0, 2.4]	3 (0.5) [0.1, 1.4]	0 [0.0, 3.2]	3 (0.3) [0.1, 1.0]	0 [0.0, 2.7]	3 (0.3) [0.1, 0.8]
Pyelonephritis	0 [0.0, 2.4]	2 (0.3) [0.0, 1.1]	0 [0.0, 3.2]	2 (0.2) [0.0, 0.8]	1(0.7) [0.0, 4.0]	3 (0.3) [0.1, 0.8]
Varicella	0 [0.0, 2.4]	2 (0.3) [0.0, 1.1]	0 [0.0, 3.2]	2 (0.2) [0.0, 0.8]	1 (0.7) [0.0, 4.0]	3 (0.3) [0.1, 0.8]
Abscess	0 [0.0, 2.4]	2 (0.3) [0.0, 1.1]	0 [0.0, 3.2]	2 (0.2) [0.0, 0.8]	0 [0.0, 2.7]	2 (0.2) [0.0, 0.7]
Campylobacter infection	2 (1.3) [0.2, 4.6]	0 [0.0, 0.6]	0 [0.0, 3.2]	2 (0.2) [0.0, 0.8]	0 [0.0, 2.7]	2 (0.2) [0.0, 0.7]
Gastroenteritis viral	0 [0.0, 2.4]	2 (0.3) [0.0, 1.1]	0 [0.0, 3.2]	2 (0.2) [0.0, 0.8]	0 [0.0, 2.7]	2 (0.2) [0.0, 0.7]
Gingivitis	0 [0.0, 2.4]	2 (0.3) [0.0, 1.1]	0 [0.0, 3.2]	2 (0.2) [0.0, 0.8]	0 [0.0, 2.7]	2 (0.2) [0.0, 0.7]
Impetigo	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	1 (0.7) [0.0, 4.0]	2 (0.2) [0.0, 0.7]
Infection susceptibility increased	0 [0.0, 2.4]	2 (0.3) [0.0, 1.1]	0 [0.0, 3.2]	2 (0.2) [0.0, 0.8]	0 [0.0, 2.7]	2 (0.2) [0.0, 0.7]
Meningitis	0 [0.0, 2.4]	0 [0.0, 0.6]	2 (1.8) [0.1, 6.4]	2 (0.2) [0.0, 0.8]	0 [0.0, 2.7]	2 (0.2) [0.0, 0.7]
Perirectal abscess	0 [0.0, 2.4]	2 (0.3) [0.0, 1.1]	0 [0.0, 3.2]	2 (0.2) [0.0, 0.8]	0 [0.0, 2.7]	2 (0.2) [0.0, 0.7]
Skin infection	0 [0.0, 2.4]	2 (0.3) [0.0, 1.1]	0 [0.0, 3.2]	2 (0.2) [0.0, 0.8]	0 [0.0, 2.7]	2 (0.2) [0.0, 0.7]
Tooth abscess	2 (1.3) [0.2, 4.6]	0 [0.0, 0.6]	0 [0.0, 3.2]	2 (0.2) [0.0, 0.8]	0 [0.0, 2.7]	2 (0.2) [0.0, 0.7]
Tooth infection	0 [0.0, 2.4]	2 (0.3) [0.0, 1.1]	0 [0.0, 3.2]	2 (0.2) [0.0, 0.8]	0 [0.0, 2.7]	2 (0.2) [0.0, 0.7]
Viral rash	0 [0.0, 2.4]	2 (0.3) [0.0, 1.1]	0 [0.0, 3.2]	2 (0.2) [0.0, 0.8]	0 [0.0, 2.7]	2 (0.2) [0.0, 0.7]

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SOC, Preferred term, n (IR/ 100 PY) (95% CI)	FCAS N= 42	MWS N=169	NOMID N= 32	All CAPS N=243	Other* N= 42	ALL N=285
Vulvovaginal candidiasis	1 (0.6) [0.0, 3.6]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	2 (0.2) [0.0, 0.8]	0 [0.0, 2.7]	2 (0.2) [0.0, 0.7]
Abscess jaw	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Abscess limb	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Acne pustular	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Anal abscess	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Appendicitis	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Bacterial infection	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Bacterial tracheitis	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Cellulitis staphylococcal	0 [0.0, 2.4]	0 [0.0, 0.6]	0 [0.0, 3.2]	0 [0.0, 0.4]	1 (0.7) [0.0, 4.0]	1 (0.1) [0.0, 0.5]
Chronic sinusitis	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Diverticulitis	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Epstein-Barr virus infection	0 [0.0, 2.4]	0 [0.0, 0.6]	0 [0.0, 3.2]	0 (0) [0.0, 0.4]	1 (0.7) [0.0, 4.0]	1 (0.1) [0.0, 0.5]
Erysipelas	0 [0.0, 2.4]	0 [0.0, 0.6]	1 (0.9) [0.0, 4.9]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Eyelid infection	0 [0.0, 2.4]	0 [0.0, 0.6]	0 [0.0, 3.2]	0 (0) [0.0, 0.4]	1 (0.7) [0.0, 4.0]	1 (0.1) [0.0, 0.5]
Furuncle	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Gastroenteritis rotavirus	0 [0.0, 2.4]	0 [0.0, 0.6]	0 [0.0, 3.2]	0 [0.0, 0.4]	1 (0.7) [0.0, 4.0]	1 (0.1) [0.0, 0.5]

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SOC, Preferred term, n (IR/ 100 PY) (95% CI)	FCAS N= 42	MWS N=169	NOMID N= 32	All CAPS N=243	Other* N= 42	ALL N=285
Latent tuberculosis	0 [0.0, 2.4]	0 [0.0, 0.6]	0 [0.0, 3.2]	0 [0.0, 0.4]	1 (0.7) [0.0, 4.0]	1 (0.1) [0.0, 0.5]
Localized infection	0 [0.0, 2.4]	0 [0.0, 0.6]	1 (0.9) [0.0, 4.9]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Lung infection	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Mastitis	1 (0.6) [0.0, 3.6]	0 [0.0, 0.6]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Meningitis aseptic	0 [0.0, 2.4]	0 [0.0, 0.6]	1 (0.9) [0.0, 4.9]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Meningitis bacterial	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Molluscum contagiosum	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Otitis media	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Parvovirus B19 infection	0 [0.0, 2.4]	0 [0.0, 0.6]	0 [0.0, 3.2]	0 [0.0, 0.4]	1 (0.7) [0.0, 4.0]	1 (0.1) [0.0, 0.5]
Periorbital cellulitis	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Pilonidal cyst	0 [0.0, 2.4]	0 [0.0, 0.6]	1 (0.9) [0.0, 4.9]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Postoperative wound infection	0 [0.0, 2.4]	0 [0.0, 0.6]	0 [0.0, 3.2]	0 [0.0, 0.4]	1 (0.7) [0.0, 4.0]	1 (0.1) [0.0, 0.5]
Pyelonephritis acute	0 [0.0, 2.4]	0 [0.0, 0.6]	0 [0.0, 3.2]	0 [0.0, 0.4]	1 (0.7) [0.0, 4.0]	1 (0.1) [0.0, 0.5]
Rhinovirus infection	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Scarlet fever	0 [0.0, 2.4]	0 [0.0, 0.6]	0 [0.0, 3.2]	0 [0.0, 0.4]	1 (0.7) [0.0, 4.0]	1 (0.1) [0.0, 0.5]
Staphylococcal infection	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]

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SOC, Preferred term, n (IR/ 100 PY) (95% CI)	FCAS N= 42	MWS N=169	NOMID N= 32	All CAPS N=243	Other* N= 42	ALL N=285
Subcutaneous abscess	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Tinea cruris	0 [0.0, 2.4]	0 [0.0, 0.6]	1 (0.9) [0.0, 4.9]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Tracheitis	0 [0.0, 2.4]	0 [0.0, 0.6]	0 [0.0, 3.2]	0 [0.0, 0.4]	1 (0.7) [0.0, 4.0]	1 (0.1) [0.0, 0.5]
Vaccination site cellulitis	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Viral diarrhoea	0 [0.0, 2.4]	0 [0.0, 0.6]	0 [0.0, 3.2]	0 [0.0, 0.4]	1 (0.7) [0.0, 4.0]	1 (0.1) [0.0, 0.5]
Viral myositis	0 [0.0, 2.4]	0 [0.0, 0.6]	0 [0.0, 3.2]	0 [0.0, 0.4]	1 (0.7) [0.0, 4.0]	1 (0.1) [0.0, 0.5]
Wound infection	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
General disorders and administration site conditions	4 (2.6) [0.7, 6.6]	62 (9.6) [7.3, 12.3]	10 (8.8) [4.2, 16.2]	76 (8.3) [6.5, 10.4]	20 (14.3) [8.7, 22.1]	96 (9.1) [7.4, 11.1]
Pyrexia	2 (1.3) [0.2, 4.6]	8 (1.2) [0.5, 2.4]	2 (1.8) [0.2, 6.3]	12 (1.3) [0.7, 2.3]	12 (8.6) [4.4, 15.0]	24 (2.3) [1.5, 3.4]
Fatigue	1 (0.6) [0.0, 3.6]	15 (2.3) [1.3, 3.8]	5 (4.4) [1.4,10.3]	21 (2.3) [1.4, 3.5]	2 (1.4) [0.2, 5.2]	23 (2.2) [1.4, 3.3]
Malaise	0 [0.0, 2.4]	4 (0.6) [0.2, 1.6]	0 [0.0, 3.2]	4 (0.4) [0.1, 1.1]	2 (1.4) [0.2, 5.2]	6 (0.6) [0.2, 1.2]
Vaccination site inflammation	0 [0.0, 2.4]	5 (0.8) [0.3, 1.8]	0 [0.0, 3.2]	5 (0.5) [0.2, 1.3]	1 (0.7) [0.0, 4.0]	6 (0.6) [0.2, 1.2]
Condition aggravated	0 [0.0, 2.4]	2 (0.3) [0.0, 1.1]	1 (0.9) [0.0, 4.9]	3 (0.3) [0.1, 1.0]	0 [0.0, 2.7]	3 (0.3) [0.1, 0.8]
Cyst	0 [0.0, 2.4]	3 (0.5) [0.1, 1.4]	0 [0.0, 3.2]	3 (0.3) [0.1, 1.0]	0 [0.0, 2.7]	3 (0.3) [0.1, 0.8]
Influenza like illness	1 (0.6) [0.0, 3.4]	2 (0.3) [0.0, 1.1]	0 [0.0, 3.2]	3 (0.3) [0.0, 1.0]	0 [0.0, 2.7]	3 (0.3) [0.1, 1.0]

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Supplemental material

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RMD Open

SOC, Preferred term, n (IR/ 100 PY) (95% CI)	FCAS N= 42	MWS N=169	NOMID N= 32	All CAPS N=243	Other* N= 42	ALL N=285
Injection site pain	0 [0.0, 2.4]	2 (0.3) [0.0, 1.1]	0 [0.0, 3.2]	2 (0.2) [0.0, 0.8]	1 (0.7) [0.0, 4.0	3 (0.3) [0.1, 0.8]
Injection site reaction	0 [0.0, 2.4]	3 (0.5) [0.1, 1.4]	0 [0.0, 3.2]	3 (0.3) [0.1, 1.0]	0 [0.0, 2.7]	3 (0.3) [0.1, 0.8]
Vaccination site reaction	0 [0.0, 2.4]	2 (0.3) [0.0, 1.1]	1 (0.9) [0.0, 4.9]	3 (0.3) [0.1, 1.0]	0 [0.0, 2.7]	3 (0.3) [0.1, 0.8]
Drug ineffective	0 [0.0, 2.4]	2 (0.3) [0.0, 1.1]	0 [0.0, 3.2]	2 (0.2) [0.0, 0.8]	0 [0.0, 2.7]	2 (0.2) [0.0 0.7]
Vaccination site erythema	0 [0.0, 2.4]	2 (0.3) [0.0, 1.1]	0 [0.0, 3.2]	2 (0.2) [0.0, 0.8]	0 [0.0, 2.7]	2 (1.0) [0.0, 0.7]
Adverse drug reaction	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (1.0) [0.0, 0.5]
Asthenia	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Chest pain	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Feeling cold	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Hunger	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Immediate post-injection reaction	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 (0) [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 (0) [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Impaired healing	0 [0.0, 2.4]	0 [0.0, 0.6]	1 (0.9) [0.0, 4.9]	1 (0.1) [0.0, 0.6]	0 (0) [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Injection site erythema	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Injection site hematoma	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Injection site irritation	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]

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SOC, Preferred term, n (IR/ 100 PY) (95% CI)	FCAS N= 42	MWS N=169	NOMID N= 32	All CAPS N=243	Other* N= 42	ALL N=285
Localized edema	0 [0.0, 2.4]	0 [0.0, 0.6]	0 [0.0, 3.2]	0 [0.0, 0.4]	1 (0.7) [0.0, 4.0]	1 (0.1) [0.0, 0.5]
Nodule	0 [0.0, 2.4]	0 [0.0, 0.6]	0 [0.0, 3.2]	0 [0.0, 0.4]	1 (0.7) [0.0, 4.0]	1 (0.1) [0.0, 0.5]
Non-cardiac chest pain	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Peripheral swelling	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Therapeutic product ineffective	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Gastrointestinal disorders	8 (5.1) [2.2, 10.1]	51 (7.9) [5.9, 10.3]	6 (5.3) [1.9, 11.5]	65 (7.1) [5.5, 9.0]	24 (17.2) [11.0, 25.6]	89 (8.4) [6.8, 10.3]
Diarrhea	1 (0.6) [0.0, 3.6]	9 (1.4) [0.6, 2.6]	3 (2.6) [0.5 7.7]	13 (1.4) [0.8, 2.4]	3 (2.1) [0.4, 6.3]	16 (1.5) [0.9, 2.5]
Abdominal pain	0 [0.0, 2.4]	3 (0.5) [0.1, 1.4]	3 (2.6) [0.5, 7.7]	6 (0.7) [0.24, 1.4]	5 (3.6) [1.2, 8.3]	11 (1.0) [0.5, 1.9]
Abdominal pain upper	0 [0.0, 2.4]	6 (0.9) [0.3, 2.0]	0 [0.0, 3.2]	6 (0.7) [0.2, 1.4]	1 (0.7) [0.0, 4.0]	7 (0.7) [0.3, 1.4]
Vomiting	0 [0.0, 2.4]	3 (0.5) [0.1, 1.4]	0 [0.0, 3.2]	3 (0.3) [0.1, 1.0]	4 (2.9) [0.8, 7.3]	7 (0.7) [0.3, 1.4]
Constipation	1 (0.6) [0.0, 3.6]	4 (0.6) [0.2, 1.6]	0 [0.0, 3.2]	5 (0.5) [0.2, 1.3]	1 (0.7) [0.0, 4.0]	6 (0.6) [0.2, 1.2]
Pancreatitis	0 [0.0, 2.4]	6 (0.9) [0.3, 2.0]	0 [0.0, 3.2]	6 (0.7) [0.2, 1.4]	0 [0.0, 2.7]	6 (0.6) [0.2, 1.2]
Anal fissure	0 [0.0, 2.4]	2 (0.3) [0.0, 1.1]	0 [0.0, 3.2]	2 (0.2) [0.0, 0.8]	2 (1.4) [0.2, 5.2]	4 (0.4) [0.1, 1.0]
Aphthous ulcer	2 (1.3) [0.2, 4.6]	2 (0.3) [0.0, 1.1]	0 [0.0, 3.2]	4 (0.4) [0.1, 1.1]	0 [0.0, 2.7]	4 (0.4) [0.1, 1.0]
Gastroesophageal	1 (0.6) [0.0, 3.4]	3 (0.5) [0.1, 1.4]	0 [0.0, 3.2]	4 (0.4) [0.1, 1.1]	0 [0.0, 2.7]	4 (0.4) [0.1, 1.0]

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SOC, Preferred term, n (IR/ 100 PY) (95% CI)	FCAS N= 42	MWS N=169	NOMID N= 32	All CAPS N=243	Other* N= 42	ALL N=285
reflux disease						
Gastritis	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	2 (1.4) [0.2, 5.2]	3 (0.3) [0.1, 1.0]
Dental necrosis	0 [0.0, 2.4]	2 (0.3) [0.0, 1.1]	0 [0.0, 3.2]	2 (0.2) [0.0, 0.8]	0 [0.0, 2.7]	2 (0.2) [0.0, 0.7]
Gingival pain	1 (0.6) [0.0, 3.6]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	2 (0.2) [0.0, 0.8]	0 [0.0, 2.7]	2 (0.2) [0.0, 0.7]
Mouth ulceration	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	1 (0.7) [0.0, 4.0]	2 (0.2) [0.0, 0.7]
Abdominal hernia	1 (0.6) [0.0, 3.6]	0 [0.0, 0.6]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Abdominal pain lower	0 [0.0, 2.4]	0 [0.0, 0.6]	0 [0.0, 3.2]	0 [0.0, 0.4]	1 (0.7) [0.0, 4.0]	1 (0.1) [0.0, 0.5]
Dental caries	1 (0.6) [0.0, 3.6]	0 [0.0, 0.6]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Dyspepsia	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Enterocolitis	0 [0.0, 2.4]	0 [0.0, 0.6]	0 [0.0, 3.2]	0 [0.0, 0.4]	1 (0.7) [0.0, 4.0]	1 (0.1) [0.0, 0.5]
Flatulence	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Gastrointestinal toxicity	0 [0.0, 2.4]	0 (0) [0.0, 0.6]	0 [0.0, 3.2]	0 [0.0, 0.4]	1 (0.7) [0.0, 4.0]	1 (0.1) [0.0, 0.5]
Haemorrhoids	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Inguinal hernia	0 [0.0, 2.4]	0 [0.0, 0.6]	0 [0.0, 3.2]	0 [0.0, 0.4]	1 (0.7) [0.0, 4.0]	1 (0.1) [0.0, 0.5]
Large intestine polyp	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Lip blister	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]

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SOC, Preferred term, n (IR/ 100 PY) (95% CI)	FCAS N= 42	MWS N=169	NOMID N= 32	All CAPS N=243	Other* N= 42	ALL N=285
Nausea	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Noninfective gingivitis	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Odynophagia	0 [0.0, 2.4]	0 (0) [0.0, 0.6]	0 [0.0, 3.2]	0 [0.0, 0.4]	1 (0.7) [0.0, 4.0]	1 (0.1) [0.0, 0.5]
Umbilical hernia	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Musculoskeletal and connective tissue disorders	8 (5.1) [2.2, 10.1]	35 (5.4) [3.8, 7.5]	4 (3.5) [1.0, 9.0]	47 (5.1) [3.8, 6.8]	21 (15.0) [9.3, 23.0]	68 (6.4) [5.0, 8.2]
Arthralgia	2(1.3) [0.2, 4.6]	6 (0.9) [0.3, 2.0]	0 [0.0, 3.2]	8 (0.9) [0.4, 1.7]	3 (2.1) [0.4, 6.3]	11 (1.0) [0.5, 1.9]
Back pain	1 (0.6) [0.0, 3.6]	5 (0.8) [0.3, 1.8]	0 [0.0, 3.2]	6 (0.7) [0.2, 1.4]	2 (1.4) [0.2, 5.2]	8 (0.8) [0.3, 1.5]
Pain in extremity	1(0.6) [0.0, 3.6]	3 (0.5) [0.1, 1.4]	0 [0.0, 3.2]	4 (0.4) [0.1, 1.2]	3 (2.2) [0.4, 6.3]	7 (0.7) [0.3, 1.4]
Synovitis	0 [0.0, 2.4]	4 (0.6) [0.2, 1.6]	0 [0.0, 3.2]	4 (0.4) [0.1, 1.1]	0 [0.0, 2.7]	4 (0.4) [0.1, 1.0]
Muscle spasms	0 [0.0, 2.4]	3 (0.5) [0.1, 1.4]	0 [0.0, 3.2]	3 (0.3) [0.1, 1.0]	0 [0.0, 2.7]	3 (0.3) [0.1, 0.8]
Musculoskeletal pain	1 (0.6) [0.0, 3.6]	1(0.2) [0.0, 0.9]	0 [0.0, 3.2]	2 (0.2) [0.0, 0.8]	1 (0.7) [0.0, 4.0]	3 (0.3) [0.1, 0.8]
Neck pain	1 (0.6) [0.0, 3.6]	1(0.2) [0.0, 0.9]	0 [0.0, 3.2]	2 (0.2) [0.0, 0.8]	1 (0.7) [0.0, 4.0]	3 (0.3) [0.1, 0.8]
Coccydynia	1 (0.6) [0.0, 3.6]	0 [0.0, 0.6]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	1 (0.7) [0.0, 4.0]	2 (0.2) [0.0, 0.7]
Knee deformity	0 [0.0, 2.4]	0 [0.0, 0.6]	2 (1.8) [0.2, 6.3]	2 (0.2) [0.0, 0.8]	0 [0.0, 2.7]	2 (0.2) [0.0, 0.7]
Myalgia	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.2) [0.0, 0.6]	1 (0.7) [0.0, 4.0]	2 (0.2) [0.0, 0.7]

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SOC, Preferred term, n (IR/ 100 PY) (95% CI)	FCAS N= 42	MWS N=169	NOMID N= 32	All CAPS N=243	Other* N= 42	ALL N=285
Plantar fasciitis	0 [0.0, 2.4]	2 (0.3) [0.0, 1.1]	0 [0.0, 3.2]	2 (0.2) [0.0, 0.8]	0 [0.0, 2.7]	2 (0.2) [0.0, 0.7]
Synovial cyst	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	1 (0.7) [0.0, 4.0]	2 (0.2) [0.0, 0.7]
Tendonitis	1 (0.6) [0.0, 3.6]	0 [0.0, 0.6]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	1 (0.7) [0.0, 4.0]	2 (0.2) [0.0, 0.7]
Acquired claw toe	0 [0.0, 2.4]	0 [0.0, 0.6]	0 [0.0, 3.2]	0 [0.0, 0.4]	1 (0.7) [0.0, 4.0]	1 (0.1) [0.0, 0.5]
Arthropathy	0 [0.0, 2.4]	0 [0.0, 0.6]	0 [0.0, 3.2]	0 [0.0, 0.4]	1 (0.7) [0.0, 4.0]	1 (0.1) [0.0, 0.5]
Bursitis	0 [0.0, 2.4]	0 [0.0, 0.6]	0 [0.0, 3.2]	0 [0.0, 0.4]	1 (0.7) [0.0, 4.0]	1 (0.1) [0.0, 0.5]
Chondropathy	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 (0) [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Costochondritis	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 (0) [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Fibromyalgia	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 (0) [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Interventional disc protrusion	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Joint swelling	0 [0.0, 2.4]	0 [0.0, 0.6]	1 (0.9) [0.0, 4.9]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Joint warmth	0 [0.0, 2.4]	0 [0.0, 0.6]	1 (0.9) [0.0, 4.9]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Limb discomfort	0 [0.0, 2.4]	0 [0.0, 0.6]	0 [0.0, 3.2]	0 [0.0, 0.4]	1 (0.7) [0.0, 4.0]	1 (0.1) [0.0, 0.5]
Lumbar spinal stenosis	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Musculoskeletal chest pain	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]

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SOC, Preferred term, n (IR/ 100 PY) (95% CI)	FCAS N= 42	MWS N=169	NOMID N= 32	All CAPS N=243	Other* N= 42	ALL N=285
Musculoskeletal stiffness	0 [0.0, 2.4]	0 [0.0, 0.6]	0 [0.0, 3.2]	0 [0.0, 0.4]	1 (0.7) [0.0, 4.0]	1 (0.1) [0.0, 0.5]
Osteoporosis	0 [0.0, 2.4]	0 [0.0, 0.6]	0 [0.0, 3.2]	0 [0.0, 0.4]	1 (0.7) [0.0, 4.0]	1 (0.1) [0.0, 0.5]
Sacroiliitis	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Scoliosis	0 [0.0, 2.4]	0 [0.0, 0.6]	0 [0.0, 3.2]	0 [0.0, 0.4]	1 (0.7) [0.0, 4.0]	1 (0.1) [0.0, 0.5]
Tendon pain	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Nervous system disorders	5 (3.2) [1.0, 7.5]	33 (5.1) [3.5, 7.1]	17 (15.0) [8.7, 23.9]	55 (6.0) [4.5, 7.8]	11 (7.9) [3.9, 14.1]	66 (6.2) [4.8, 7.9]
Headache	2 (1.3) [0.2, 4.6]	12 (1.9) [1.0, 3.2]	10 (8.8) [4.2,16.2]	24 (2.6) [1.7, 3.9]	7 (5.0) [2.0,10.3]	31 (2.9) [2.0, 4.2]
Dizziness	1(0.6) [0.0, 3.6]	4 (0.6) [0.2, 1.6]	1 (0.9) [0.0, 4.9]	6 (0.7) [0.2, 1.4]	1 (0.7) [0.0, 4.0]	7 (0.7) [0.3, 1.4]
Syncope	0 [0.0, 2.4]	3 (0.5) [0.1, 1.4]	2 (1.8) [0.2, 6.4]	5 (0.5) [0.2, 1.3]	0 [0.0, 2.7]	5 (0.5) [0.2, 1.1]
Intracranial pressure increased	0 [0.0, 2.4]	0 [0.0, 0.6]	2 (1.8) [0.2, 6.4]	2 (0.2) [0.0, 0.8]	1 (0.7) [0.0, 4.0]	3 (0.3) [0.1, 0.8]
Paraesthesia	0 [0.0, 2.4]	3 (0.5) [0.1, 1.4]	0 [0.0, 3.2]	3 (0.3) [0.1, 1.0]	0 [0.0, 2.7]	3 (0.3) [0.1, 0.8]
Migraine	1 (0.6) [0.0, 3.6]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	2 (0.2) [0.0, 0.8]	0 [0.0, 2.7]	2 (0.2) [0.0, 0.7]
Sciatica	0 [0.0, 2.4]	2 (0.3) [0.0, 1.1]	0 [0.0, 3.2]	2 (0.2) [0.0, 0.8]	0 [0.0, 2.7]	2 (0.2) [0.0, 0.7]
Amnesia	0 [0.0, 2.4]	0 [0.0, 0.6]	0 [0.0, 3.2]	0 [0.0, 0.4]	1 (0.7) [0.0, 4.0]	1 (0.1) [0.0, 0.5]
Brain mass	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]

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SOC, Preferred term, n (IR/ 100 PY) (95% CI)	FCAS N= 42	MWS N=169	NOMID N= 32	All CAPS N=243	Other* N= 42	ALL N=285
Carpal tunnel syndrome	0 [0.0, 2.4]	0 [0.0, 0.6]	1 (0.8) [0.0, 4.9]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Cerebral infarction	1 (0.6) [0.0, 3.6]	0 [0.0, 0.6]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Demyelination	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Epilepsy	0 [0.0, 2.4]	0 [0.0, 0.6]	1 (0.9) [0.0, 4.9]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Hypoaesthesia	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Nervous system disorder	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.53]
Psychomotor hyperactivity	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Seizure	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Sensory loss	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Facial nerve paralysis	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Visual field defect	0 [0.0, 2.4]	0 [0.0, 0.6]	0 [0.0, 3.2]	0 [0.0, 0.4]	1 (0.7) [0.0, 4.0]	1 (0.1) [0.0, 0.5]
Respiratory, thoracic and mediastinal disorders	3 (1.9) [0.4, 5.6]	32 (4.9) [3.4, 7.0]	2 (1.8) [0.2, 6.3]	37 (4.0) [2.8, 5.6]	17 (12.2) [7.1, 19.5]	54 (5.1) [3.8, 6.7]
Cough	1 (0.6) [0.0, 3.6]	7 (1.1) [0.4, 2.2]	1 (0.9) [0.0, 4.9]	8 (0.9) [0.5, 1.9]	7 (5.0) [2.0, 10.3]	16 (1.5) [0.9, 2.5]
Oropharyngeal pain	2 (1.3) [0.2, 4.6]	5 (0.8) [0.3, 1.8]	1 (0.9) [0.0, 4.9]	8 (0.9) [0.4, 1.7]	4 (2.9) [0.8, 7.3]	12 (1.1) [0.6, 2.0]

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SOC, Preferred term, n (IR/ 100 PY) (95% CI)	FCAS N= 42	MWS N=169	NOMID N= 32	All CAPS N=243	Other* N= 42	ALL N=285
Dyspnea	0 [0.0, 2.4]	4 (0.6) [0.2, 1.6]	0 [0.0, 3.2]	4 (0.4) [0.1, 1.1]	2 (1.4) [0.2, 5.2]	6 (0.6) [0.2, 1.2]
Asthma	0 [0.0, 2.4]	4 (0.6) [0.2, 1.6]	0 [0.0, 3.2]	4 (0.4) [0.1, 1.1]	1 (0.7) [0.0, 4.0]	5 (0.5) [0.2, 1.1]
Rhinitis allergic	0 [0.0, 2.4]	3 (0.5) [0.1, 1.4]	0 [0.0, 3.2]	3 (0.3) [0.1, 1.0]	0 [0.0, 2.7]	3 (0.3) [0.1, 0.9]
Sleep apnoea syndrome	0 [0.0, 2.4]	2 (0.3) [0.0, 1.1]	0 [0.0, 3.2]	2 (0.2) [0.0, 0.8]	0 [0.0, 2.7]	2 (0.2) [0.0, 0.7]
Acute respiratory distress syndrome	0 [0.0, 2.4]	0 [0.0, 0.6]	0 [0.0, 3.2]	0 [0.0, 0.4]	1 (0.7) [0.0, 4.0]	1 (0.1) [0.0, 0.5]
Adenoidal hypertrophy	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Bronchial disorder	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Bronchitis chronic	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Dysphonia	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Nasal discharge discolouration	0 [0.0, 2.4]	0 [0.0, 0.6]	0 [0.0, 3.2]	0 [0.0, 0.4]	1 (0.7) [0.0, 4.0]	1 (0.1) [0.0, 0.5]
Nasal turbinate hypertrophy	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Pleural effusion	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Rhinorrhoea	0 [0.0, 2.4]	0 [0.0, 0.6]	0 [0.0, 3.2]	0 [0.0, 0.4]	1 (0.7) [0.0, 4.0]	1 (0.1) [0.0, 0.5]
Sinus congestion	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Investigations	9 (5.8) [2.6, 11.0]	30 (4.6) [3.1, 6.6]	7 (6.2) [2.5, 12.7]	46 (5.0) [3.7, 6.7]	1 (0.7) [0.0, 4.0]	47 (4.4) [3.3, 5.9]

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SOC, Preferred term, n (IR/ 100 PY) (95% CI)	FCAS N= 42	MWS N=169	NOMID N= 32	All CAPS N=243	Other* N= 42	ALL N=285
Protein urine present	4 (2.6) [0.7, 6.6]	3 (0.5) [0.1, 1.4]	5 (4.4) [1.4,10.3]	12 (1.3) [0.7, 2.3]	0 [0.0, 2.7]	12 (1.1) [0.6, 2.0]
Weight gain	1(0.6) [0.0, 3.6]	9 (1.4) [0.6, 2.6]	0 [0.0, 3.2]	10 (1.1) [0.5, 2.0]	0 [0.0, 2.7]	10 (0.9) [0.5, 1.7]
Antinuclear antibody positive	0 [0.0, 2.4]	4 (0.6) [0.2, 1.6]	0 [0.0, 3.2]	4 (0.4) [0.1, 1.1]	0 [0.0, 2.7]	4 (0.4) [0.1, 1.0]
Hypercholesterolemia	3 (1.9) [0.4, 5.6]	0 [0.0, 0.6]	1 (0.9) [0.0, 4.9]	4 (0.4) [0.1, 1.1]	0 [0.0, 2.7]	4 (0.4) [0.1, 1.0]
Liver enzymes elevated	1 (0.6) [0.0, 3.6]	3 (0.5) [0.1, 1.4]	0 [0.0, 3.2]	4 (0.4) [0.1, 1.1]	0 [0.0, 2.7]	4 (0.4) [0.1, 1.0]
Gamma-glutamyl transferase increased	0 [0.0, 2.4]	3 (0.5) [0.1, 1.4]	0 [0.0, 3.2]	3 (0.3) [0.1, 1.0]	0 [0.0, 2.7]	3 (0.3) [0.1, 0.9]
Low density lipoprotein increased	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	1 (0.9) [0.0, 4.9]	2 (0.2) [0.0, 0.8]	0 [0.0, 2.7]	2 (0.2) [0.0, 0.7]
Alanine aminotransferase increased	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Aspartate aminotransferase increased	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Blood creatinine phosphokinase increased	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Blood glucose increased	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]

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SOC, Preferred term, n (IR/ 100 PY) (95% CI)	FCAS N= 42	MWS N=169	NOMID N= 32	All CAPS N=243	Other* N= 42	ALL N=285
Creatinine renal clearance decreased	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Haemoglobin decreased	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 (0) [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 (0) [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Serum amyloid A protein increased	0 [0.0, 2.4]	0 [0.0, 0.6]	0 [0.0, 3.2]	0 [0.0, 0.4]	1 (0.7) [0.0, 4.0]	1 (0.1) [0.0, 0.5]
Urine protein/creatinine ratio increased	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Ear and labyrinth disorders	2 (1.3) [0.2, 4.6]	28 (4.3) [2.9, 6.2]	12 (10.5) [5.5, 18.4]	42 (4.6) [3.3, 6.2]	4 (2.9) [0.8, 7.3]	46 (4.3)[3.2, 5.8]
Vertigo	1 (0.6) [0.0, 3.6]	21 (3.2) [2.0, 5.0]	9 (7.9) [3.6,15.0]	31 (3.4) [2.3, 4.8]	3 (2.2) [0.4, 6.3]	34 (3.2)[2.2, 4.5]
Ear pain	0 [0.0, 2.4]	2 (0.3) [0.0, 1.1]	0 [0.0, 3.2]	2 (0.) [0.0, 0.8]	0 [0.0, 2.7]	2 (0.2) [0.0, 0.7]
Tinnitus	1 (0.6) [0.0, 3.6]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	2 (0.2) [0.0, 0.8]	0 [0.0, 2.7]	2 (0.2) [0.0, 0.7]
Tympanic membrane perforation	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	1 (0.9) [0.0, 4.9]	2 (0.2) [0.0, 0.8]	0 [0.0, 2.7]	2 (0.2) [0.0, 0.7]
Deafness	0 [0.0, 2.4]	0 [0.0, 0.6]	1 (0.9) [0.0, 4.9]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Deafness unilateral	0 [0.0, 2.4]	0 [0.0, 0.6]	0 [0.0, 3.2]	0 [0.0, 0.4]	1 (0.7) [0.0, 4.0]	1 (0.1) [0.0, 0.5]
Eustachian tube disorder	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 (0) [0.0, 2.7]	1 (0.1) [0.0, 0.5]
External ear inflammation	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 (0) [0.0, 2.7]	1 (0.1) [0.0, 0.5]

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SOC, Preferred term, n (IR/ 100 PY) (95% CI)	FCAS N= 42	MWS N=169	NOMID N= 32	All CAPS N=243	Other* N= 42	ALL N=285
Hearing impaired	0 [0.0, 2.4]	0 [0.0, 0.6]	1 (0.9) [0.0, 4.9]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Sudden hearing loss	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Skin and subcutaneous tissue damage	6 (3.9) [1.4, 8.4]	28 (4.3) [2.9, 6.2]	8 (7.0) [3.0, 13.9]	42 (4.6) [3.3, 6.2]	4 (2.9) [0.8 7.3]	46 (4.4) [3.2, 5.8]
Rash	0 [0.0, 2.4]	8 (1.2) [0.5, 2.4]	1 (0.9) [0.0, 4.9]	9 (1.0) [0.4, 1.9]	2 (1.4) [0.2, 5.2]	11 (1.0) [0.5, 1.9]
Urticaria	2 (1.3) [0.2, 4.6]	2 (0.3) [0.0, 1.1]	1 (0.9) [0.0, 4.9]	5 (0.5) [0.2, 1.3]	0 [0.0, 2.7]	5 (0.5) [0.2, 1.1]
Eczema	0 [0.0, 2.4]	3 (0.5) [0.1, 1.4]	1 (0.9) [0.0, 4.9]	4 (0.4) [0.1, 1.1]	0 [0.0, 2.7]	4 (0.4) [0.1, 1.0]
Dry skin	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	1 (0.9) [0.0, 4.9]	2 (0.2) [0.0, 0.8]	0 [0.0, 2.7]	2 (0.2) [0.0, 0.7]
Erythema	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	1 (0.9) [0.0, 4.9]	2 (0.2) [0.0, 0.8]	0 [0.0, 2.7]	2 (0.2) [0.0, 0.7]
Perivascular dermatitis	0 [0.0, 2.4]	2 (0.3) [0.0, 1.1]	0 [0.0, 3.2]	2 (0.2) [0.0, 0.8]	0 [0.0, 2.7]	2 (0.2) [0.0, 0.7]
Pruritus generalised	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	1 (0.7) [0.0, 4.0]	2 (0.2) [0.0, 0.7]
Rash erythematous	0 [0.0, 2.4]	0 [0.0, 0.6]	2 (1.8) [0.2, 6.4]	2 (0.2) [0.0, 0.8]	0 [0.0, 2.7]	2 (0.2) [0.0, 0.7]
Acne	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Alopecia	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Dermatitis atopic	0 [0.0, 2.4]	0 [0.0, 0.6]	0 [0.0, 3.2]	0 [0.0, 0.4]	1 (0.7) [0.0, 4.0]	1 (0.1) [0.0, 0.5]
Hyperhidrosis	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]

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SOC, Preferred term, n (IR/ 100 PY) (95% CI)	FCAS N= 42	MWS N=169	NOMID N= 32	All CAPS N=243	Other* N= 42	ALL N=285
Night sweats	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Pigmentation disorder	1 (0.6) [0.0, 3.6]	0 [0.0, 0.6]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Pruritus	0 [0.0, 2.4]	0 [0.0, 0.6]	1 (0.9) [0.0, 4.9]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Pruritus allergic	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Psoriasis	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Rash generalised	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Skin disorder	1 (0.6) [0.0, 3.6]	0 [0.0, 0.6]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Skin exfoliation	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Skin lesion	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Skin ulcer	1 (0.6) [0.0, 3.6]	0 [0.0, 0.6]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Swelling face	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Xanthelasma	1 (0.6) [0.0, 3.6]	0 [0.0, 0.6]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.5]
Injury, poisoning and procedural complications	6 (3.8) [1.4, 8.4]	29 (4.5) [3.0, 6.4]	0 [0.0, 3.2]	35 (3.8)[2.7, 5.3]	8 (5.7)[2.5, 11.3]	43 (4.1) [2.9, 5.5]
Fall	3 (1.9) [0.4, 5.6]	3 (0.5) [0.1, 1.4]	0 [0.0, 3.2]	6 (0.7) [0.2, 1.4]	3 (2.1) [0.4, 6.3]	9 (0.9) [0.4, 1.6]
Ligament sprain	0 [0.0, 2.4]	4 (0.6) [0.2, 1.6]	0 [0.0, 3.2]	4 (0.4) [0.1, 1.1]	1 (0.7) [0.0, 4.0]	5 (0.5) [0.2, 1.1]

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SOC, Preferred term, n (IR/ 100 PY) (95% CI)	FCAS N= 42	MWS N=169	NOMID N= 32	All CAPS N=243	Other* N= 42	ALL N=285
Vaccination complication	0 [0.0, 2.4]	4 (0.6) [0.2, 1.6]	0 [0.0, 3.2]	4 (0.4) [0.1, 1.1]	0 [0.0, 3.2]	4 (0.4) [0.1, 0.1]
Procedural headache	0 [0.0, 2.4]	3 (0.5) [0.1, 1.4]	0 [0.0, 3.2]	3 (0.3) [0.1, 1.0]	0 [0.0, 2.7]	3 (0.3) [0.1, 0.8]
Procedural nausea	0 [0.0, 2.4]	3 (0.5) [0.1, 1.4	0 [0.0, 3.2]	3 (0.3) [0.1, 1.0]	0 [0.0, 2.7]	3 (0.3) [0.1, 0.8]
Eschar	0 [0.0, 2.4]	0 [0.0, 0.6]	0 [0.0, 3.2]	0 [0.0, 0.4]	2 (1.4) [0.2, 5.2]	2 (0.2) [0.0, 0.7]
Ankle fracture	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Clavicle fracture	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Contusion	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Facial bones fracture	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Femur fracture	0 [0.0, 2.4]	0 [0.0, 0.6]	0 [0.0, 3.2]	0 [0.0, 0.4]	1 (0.7) [0.0, 4.0]	1 (0.1) [0.0, 0.5]
Forearm fracture	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Hand fracture	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Nail avulsion	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.09) [0.0, 0.5]
Overdose	1 (0.6) [0.0, 3.6]	0 [0.0, 0.6]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Post procedural complication	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Post procedural diarrhoea	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]

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SOC, Preferred term, n (IR/ 100 PY) (95% CI)	FCAS N= 42	MWS N=169	NOMID N= 32	All CAPS N=243	Other* N= 42	ALL N=285
Post procedural haemorrhage	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Procedural pain	0 [0.0, 2.4]	1 (0.2) [0.00, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.00, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Radius fracture	1 (0.6) [0.0, 3.6]	0 [0.0, 0.6]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Rib fracture	0 [0.0, 2.4]	1 (0.2) [0.00, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.00, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Tibia fracture	0 [0.0, 2.4]	0 [0.0, 0.6]	0 [0.0, 3.2]	0 [0.0, 0.4]	1 (0.7) [0.0, 4.0]	1 (0.1) [0.0, 0.5]
Vaginal laceration	1 (0.6) [0.0, 3.6]	0 [0.0, 0.6]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Eye disorders	4 (2.6) [0.7, 6.6]	20 (3.1) [1.9, 4.8]	5 (4.4) [1.4, 10.3]	29 (3.2) [2.1, 4.5]	5 (3.6) [1.2, 8.3]	34 (3.2) [2.2, 4.5]
Cataract	0 [0.0, 2.4]	4 (0.6) [0.2, 1.6]	0 [0.0, 3.2]	4 (0.4) [0.1, 1.1]	0 [0.0, 2.7]	4 (0.4) [0.1, 0.2]
Iritis	1 (0.6) [0.0, 3.6]	2 (0.3) [0.0, 1.1]	0 [0.0, 3.2]	3 (0.3) [0.1, 1.0]	0 [0.0, 2.7]	3 (0.3) [0.1, 0.8]
Uveitis	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	1 (0.9) [0.0, 4.9]	2 (0.2) [0.0, 0.8]	1 (0.7) [0.0, 4.0]	3 (0.3) [0.1, 0.8]
Eye inflammation	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	1 (0.7) [0.0, 4.0]	2 (0.2) [0.0, 0.7]
Eye pruritus	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	1 (0.9) [0.0, 5.0]	2 (0.2) [0.0, 0.8]	0 [0.0, 2.7]	2 (0.2) [0.0, 0.7]
Glaucoma	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	1 (0.9) [0.0, 4.9]	2 (0.2) [0.0, 0.8]	0 [0.0, 2.7]	2 (0.2) [0.0, 0.7]
Iridocyclitis	2 (1.3) [0.2, 4.6]	0 [0.0, 0.6]	0 [0.0, 3.2]	2 (0.2) [0.0, 0.8]	0 [0.0, 2.7]	2 (0.2) [0.0, 0.7]
Ocular hyperaemia	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	1 (0.7) [0.0, 4.0]	2 (0.2) [0.0, 0.7]

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SOC, Preferred term, n (IR/ 100 PY) (95% CI)	FCAS N= 42	MWS N=169	NOMID N= 32	All CAPS N=243	Other* N= 42	ALL N=285
Papilloedema	0 [0.0, 2.4]	2 (0.3) [0.0, 1.1]	0 [0.0, 3.2]	2 (0.2) [0.0, 0.8]	0 [0.0, 2.7]	2 (0.2) [0.0, 0.7]
Arcus lipoides	1 (0.6) [0.0, 3.6]	0 [0.0, 0.6]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Blepharitis	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Blindness	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Conjunctival hyperaemia	0 [0.0, 2.4]	0 0 [0.0, 0.6]	1 (0.9) [0.0, 4.9]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Diplopia	0 [0.0, 2.4]	0 0 [0.0, 0.6]	1 (0.9) [0.0, 4.9]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Dry eye	0 [0.0, 2.4]	0 0 [0.0, 0.6]	0 [0.0, 3.2]	0 [0.0, 0.4]	1 (0.72) [0.0, 4.0]	1 (0.1) [0.0, 0.5]
Episcleritis	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.61	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Eye pain	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Eyelid rash	0 [0.0, 2.4]	0 0 [0.0, 0.6]	0 [0.0, 3.2]	0 [0.0, 0.4]	1 (0.7) [0.0, 4.0]	1 (0.1) [0.0, 0.5]
Lacrimation increased	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Photophobia	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Visual acuity reduced	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Blood and lymphatic system disorders	0 [0.0, 2.4]	9 (1.4) [0.6, 2.6]	1 (0.9) [0.0, 4.9]	10 (1.1) [0.5, 2.0]	5 (3.6) [1.2, 8.4]	15 (1.4) [0.8, 2.3]
Anaemia	0 [0.0, 2.4]	3 (0.5) [0.1, 1.4]	0 [0.0, 3.2]	3 (0.3) [0.1, 1.0]	0 [0.0, 2.7]	3 (0.3) [0.1, 0.8]
Iron deficiency anaemia	0 [0.0, 2.4]	2 (0.3) [0.0, 1.1]	0 [0.0, 3.2]	2 (0.2) [0.0, 0.8]	0 [0.0, 2.7]	2 (0.2) [0.0, 0.7]

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SOC, Preferred term, n (IR/ 100 PY) (95% CI)	FCAS N= 42	MWS N=169	NOMID N= 32	All CAPS N=243	Other* N= 42	ALL N=285
Lymphadenopathy	0 [0.0, 2.4]	2 (0.3) [0.0, 1.1]	0 [0.0, 3.2]	2 (0.2) [0.0, 0.8]	0 [0.0, 2.7]	2 (0.2) [0.0, 0.7]
Lymphopenia	0 [0.0, 2.4]	0 [0.0, 0.6]	0 [0.0, 3.2]	0 [0.0, 0.4]	2 (1.4) [0.2, 5.2	2 (0.2) [0.0, 0.7]
Thrombocytopenia	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	1 (0.7) [0.0, 4.0]	2 (0.2) [0.0, 0.7]
Increased tendency to bruise	0 [0.0, 2.4]	0 [0.0, 0.6]	1 (0.9) [0.0, 4.9]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Lymphocytic infiltration	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Microcytosis	0 [0.0, 2.4]	0 [0.0, 0.6]	0 [0.0, 3.2]	0 [0.0, 0.4]	1 (0.7) [0.0, 4.0]	1 (0.1) [0.0, 0.5]
Neutropenia	0 [0.0, 2.4]	0 [0.0, 0.6]	0 [0.0, 3.2]	0 [0.0, 0.4]	1 (0.7) [0.0, 4.0]	1 (0.1) [0.0, 0.5]
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (0.6) [0.0, 3.6]	13 (2.0) [1.1, 3.4]	0 [0.0, 3.2]	14 (1.5) [0.8, 2.6]	1 (0.7) [0.0, 4.0]	15 (1.4) [0.8, 2.3]
Rectal cancer	0 [0.0, 2.4]	3 (0.5) [0.1, 1.4]	0 [0.0, 3.2]	3 (0.3) [0.1, 1.0]	0 [0.0, 2.7]	3 (0.3) [0.1, 0.8]
Melanocyte naevus	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	1 (0.7) [0.0, 4.0]	2 (0.2) [0.0, 0.7]
Uterine leiomyoma	0 [0.0, 2.4]	2 (0.3) [0.0, 1.1]	0 [0.0, 3.2]	2 (0.2) [0.0, 0.8]	0 [0.0, 2.7]	2 (0.2) [0.0, 0.7]
Adenocarcinoma	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Basal cell carcinoma	1 (0.6) [0.0, 3.6]	0 [0.0, 0.6]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Gastrointestinal neoplasm	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]

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SOC, Preferred term, n (IR/ 100 PY) (95% CI)	FCAS N= 42	MWS N=169	NOMID N= 32	All CAPS N=243	Other* N= 42	ALL N=285
Lipoma	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Meningioma	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Neurilemmoma benign	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Neurofibroma	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Prostate cancer	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Cardiac disorders	0 [0.0, 2.4]	11 (1.7) [0.9, 3.0]	0 [0.0, 3.2]	11 (1.2) [0.6, 2.1]	3 (2.2) [0.4, 6.3]	14 (1.3) [0.7, 2.2]
Angina pectoris	0 [0.0, 2.4]	5 (0.8) [0.3, 1.8]	0 [0.0, 3.2]	5 (0.5) [0.2, 1.3]	0 [0.0, 2.7]	5 (0.5) [0.2, 1.1]
Pericardial effusion	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	1 (0.7) [0.02, 4.0]	2 (0.2) [0.0, 0.7]
Coronary artery disease	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Extrasystoles	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Mitral valve incompetence	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Palpitations	0 [0.0, 2.4]	0 [0.0, 0.6]	0 [0.0, 3.2]	0 [0.0, 0.4]	1 (0.7) [0.02, 4.0]	1 (0.1) [0.0, 0.5]
Supraventricular extrasystoles	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Tachycardia	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Ventricular tachycardia	0 [0.0, 2.4]	0 [0.0, 0.6]	0 [0.0, 3.2]	0 [0.0, 0.4]	1 (0.7) [0.0, 4.0]	1 (0.1) [0.0, 0.5]

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SOC, Preferred term, n (IR/ 100 PY) (95% CI)	FCAS N= 42	MWS N=169	NOMID N= 32	All CAPS N=243	Other* N= 42	ALL N=285
Vascular disorders	1 (0.6) [0.0, 3.6]	11 (1.7) [0.8, 3.0]	0 [0.0, 3.2]	12 (1.3) [0.7, 2.3]	1 (0.7) [0.0, 4.0]	13 (1.2) [0.7, 2.1]
Hypertension	1 (0.6) [0.0, 3.6]	2 (0.3) [0.0, 1.1]	0 [0.0, 3.2]	3 (0.3) [0.1, 1.0]	0 [0.0, 2.7]	3 (0.3) [0.1, 0.8]
Peripheral venous disease	0 [0.0, 2.4]	2 (0.3) [0.0, 1.1]	0 [0.0, 3.2]	2 (0.2) [0.0, 0.8]	0 [0.0, 2.7]	2 (0.2) [0.0, 0.7]
Circulatory collapse	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Haematoma	0 [0.0, 2.4]	0 [0.0, 0.6]	0 [0.0, 3.2]	0 [0.0, 0.4]	1 (0.7) [0.0, 4.0]	1 (0.1) [0.0, 0.5]
Hot flush	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Lymphoedema	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Peripheral arterial occlusive disease	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Phlebitis	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Post thrombotic syndrome	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Vein disorder	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Psychiatric disorders	0 [0.0, 2.4]	9 (1.4) [0.6, 2.6]	1 (0.9) [0.0, 4.9]	10 (1.1) [0.5, 2.0]	2 (1.4) [0.2, 5.2]	12 (1.1) [0.6, 2.0]
Depression	0 [0.0, 2.4]	4 (0.6) [0.2 1.6]	1 (0.9) [0.0, 4.9]	5 (0.5) [0.2 1.3]	0 [0.0, 2.7]	5 (0.5) [0.2, 1.1]
Insomnia	0 [0.0, 2.4]	2 (0.3) [0.0, 1.1]	0 [0.0, 3.2]	2 (0.2) [0.0, 0.8]	0 [0.0, 2.7]	2 (0.2) [0.0, 0.7]
Agitation	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]

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SOC, Preferred term, n (IR/ 100 PY) (95% CI)	FCAS N= 42	MWS N=169	NOMID N= 32	All CAPS N=243	Other* N= 42	ALL N=285
Anxiety	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Fear of injection	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Nervousness	0 [0.0, 2.4]	0 [0.0, 0.6]	0 [0.0, 3.2]	0 [0.0, 0.4]	1 (0.7) [0.0, 4.0]	1 (1.0) [0.0, 0.5]
Somnambulism	0 [0.0, 2.4]	0 [0.0, 0.6]	0 [0.0, 3.2]	0 [0.0, 0.4]	1 (0.7) [0.0, 4.0]	1 (1.0) [0.0, 0.5]
Congenital, familial and genetic disorders	0 [0.0, 2.4]	4 (0.6) [0.2, 1.6]	0 [0.0, 3.2]	4 (0.4) [0.1, 1.1]	6 (4.3) [1.6, 9.3]	10 (0.9) [0.5, 1.7]
Cryopyrin associated periodic syndrome	0 [0.0, 2.4]	3 (0.5) [0.1, 1.4]	0 [0.0, 3.2]	3 (0.3) [0.1, 1.0]	2 (1.4) [0.2, 5.2]	5 (0.5) [0.2, 1.1]
Familial Mediterranean fever	0 [0.0, 2.4]	0 [0.0, 0.6]	0 [0.0, 3.2]	0 [0.0, 0.4]	3 (2.2) [0.4, 6.3]	3 (0.3) [0.1, 0.8]
Gilbert's syndrome	0 [0.0, 2.4]	0 [0.0, 0.6]	0 [0.0, 3.2]	0 [0.0, 0.4]	1 (0.7) [0.0, 4.0]	1 (0.1) [0.0, 0.5]
Hereditary neuropathy with liability to pressure palsies	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Hepatobiliary disorders	0 [0.0, 2.4]	5 (0.8) [0.3, 1.8]	0 [0.0, 3.2]	5 (0.5) [0.2, 1.3]	4 (2.9) [0.8, 7.3]	9 (0.9) [0.4, 1.6]
Cholelithiasis	0 [0.0, 2.4]	3 (0.5) [0.1, 1.4]	0 [0.0, 3.2]	3 (0.3) [0.1, 1.0]	0 [0.0, 2.7]	3 (0.3) [0.1, 0.8]
Autoimmune hepatitis	0 [0.0, 2.4]	0 [0.0, 0.6]	0 [0.0, 3.2]	0 [0.0, 0.4]	1 (0.7) [0.0, 4.0]	1 (0.1) [0.0, 0.5]
Cholecystitis	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]

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SOC, Preferred term, n (IR/ 100 PY) (95% CI)	FCAS N= 42	MWS N=169	NOMID N= 32	All CAPS N=243	Other* N= 42	ALL N=285
Cholestasis	0 [0.0, 2.4]	0 [0.0, 0.6]	0 [0.0, 3.2]	0 [0.0, 0.4]	1 (0.7) [0.0, 4.0]	1 (0.1) [0.0, 0.5]
Hepatic steatosis	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Hepatitis	0 [0.0, 2.4]	0 [0.0, 0.6]	0 [0.0, 3.2]	0 [0.0, 0.4]	1 (0.7) [0.0, 4.0]	1 (0.1) [0.0, 0.5]
Hyperbilirubinaemia	0 [0.0, 2.4]	0 [0.0, 0.6]	0 [0.0, 3.2]	0 [0.0, 0.4]	1 (0.7) [0.0, 4.0]	1 (0.1) [0.0, 0.5]
Immune system disorders	1 (0.6) [0.0, 3.6]	4 (0.6) [0.2, 1.6]	1 (0.9) [0.0, 4.9]	6 (0.7) [0.2, 1.4]	3 (2.1) [0.4, 6.3]	9 (0.9) [0.4, 1.6]
Hypersensitivity	0 [0.0, 2.4]	3 (0.5) [0.1, 1.4]	1 (0.9) [0.0, 4.9]	4 (0.4) [0.1, 1.1]	0 [0.0, 2.7]	4 (0.4) [0.1, 1.0]
Seasonal allergy	1 (0.6) [0.0, 3.6]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	2 (0.2) [0.0, 0.8]	1(0.7) [0.0, 4.0]	3 (0.3) [0.1, 0.8]
Allergy to arthropod bite	0 [0.0, 2.4]	0 [0.0, 0.6]	0 [0.0, 3.2]	0 [0.0, 0.4]	1 (0.7) [0.0, 4.0]	1 (0.1) [0.0, 0.5]
Drug hypersensitivity	0 [0.0, 2.4]	0 [0.0, 0.6]	0 [0.0, 3.2]	0 [0.0, 0.4]	1 (0.7) [0.0, 4.0]	1 (1.0) [0.0, 0.5]
Reproductive system and breast disorders	0 [0.0, 2.4]	8 (1.2) [0.5, 2.4]	0 [0.0, 3.2]	8 (0.9) [0.4, 1.7]	0 [0.0, 2.7]	8 (0.8) [0.3, 1.5]
Menstruation irregular	0 [0.0, 2.4]	2 (0.3) [0.0, 1.1]	0 [0.0, 3.2]	2 (0.2) [0.0, 0.8]	0 [0.0, 2.7]	2 (0.2) [0.0, 0.7]
Breast mass	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Endometriosis	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Menopausal symptoms	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Prostatitis	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]

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SOC, Preferred term, n (IR/ 100 PY) (95% CI)	FCAS N= 42	MWS N=169	NOMID N= 32	All CAPS N=243	Other* N= 42	ALL N=285
Uterine polyp	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Vulvovaginal dryness	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Metabolism and nutritional disorders	1 (0.6) [0.0, 3.6]	4 (0.6) [0.2, 1.6]	0 [0.0, 3.2]	5 (0.5) [0.2, 1.3]	0 [0.0, 2.7]	5 (0.5) [0.2, 1.1]
Diabetes mellitus	0 [0.0, 2.4]	2 (0.3) [0.0, 1.1]	0 [0.0, 3.2]	2 (0.2) [0.0, 0.8]	0 [0.0, 2.7]	2 (0.2) [0.0, 0.7]
Decreased appetite	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Increased appetite	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Type 2 diabetes mellitus	1 (0.6) [0.0, 3.6]	0 [0.0, 0.6]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Pregnancy, puerperium and perinatal conditions	0 [0.0, 2.4]	5 (0.8) [0.3, 1.8]	0 [0.0, 3.2]	5 (0.5) [0.2, 1.3]	0 [0.0, 2.7]	5 (0.5) [0.2, 1.1]
Abortion spontaneous	0 [0.0, 2.4]	3 (0.5) [0.1, 1.4]	0 [0.0, 3.2]	3 (0.3) [0.1, 1.0]	0 [0.0, 2.7]	3 (0.3) [0.1, 0.8]
Gestational diabetes	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Pregnancy	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Endocrine disorders	1 (0.6) [0.0, 3.6]	2 (0.3) [0.0, 1.1]	0 [0.0, 3.2]	3 (0.3) [0.1, 1.0]	1 (0.7) [0.0, 4.0]	4 (0.4) [0.1, 1.0]
Addison's disease	1 (0.6) [0.0, 3.6]	0 [0.0, 0.6]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Cushingoid	0 [0.0, 2.4]	0 [0.0, 0.6]	0 [0.0, 3.2]	0 [0.0, 0.4]	1 (0.7) [0.0, 4.0]	1 (0.1) [0.0, 0.5]
Hypothyroidism	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]

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SOC, Preferred term, n (IR/ 100 PY) (95% CI)	FCAS N= 42	MWS N=169	NOMID N= 32	All CAPS N=243	Other* N= 42	ALL N=285
Thyroid cyst	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Renal and urinary disorders	0 [0.0, 2.4]	4 (0.6) [0.2, 1.6]	0 [0.0, 3.2]	4 (0.4) [0.1, 1.1]	0 [0.0, 2.7]	4 (0.4) [0.1,1.0]
Proteinuria	0 [0.0, 2.4]	2 (0.3) [0.0, 1.1]	0 [0.0, 3.2]	2 (0.2) [0.0, 0.8]	0 [0.0, 2.7]	2 (0.2) [0.0, 0.7]
Enuresis	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Renal failure	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]

*Other includes atypical CAPS (n=18) and non-CAPS diagnoses (n=24); non-CAPS diagnoses include systemic juvenile idiopathic arthritis, unspecified autoinflammatory syndromes, familial Mediterranean fever, mevalonate kinase deficiency, adult-onset Still's disease, tumour necrosis factor-receptor associated periodic syndrome, Erdheim–Chester disease, Blau syndrome, and granulomatosis with polyangiitis.

AE, adverse events; CAPS, cryopyrin-associated periodic syndromes; FCAS, familial cold autoinflammatory syndrome; IL, interleukin; IR, incidence rates; MWS, Muckle–Wells syndrome; n, number of events; NOMID, neonatal-onset multisystem inflammatory disease; PY, patient-years; SOC, system organ class.

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Table S6 Frequency of adverse events by baseline canakinumab dose

	FCAS (N=42)	MWS (N=169)	NOMID (N=32)	All CAPS (N=243)	Other* (N=42)	ALL (N=285)
Adverse events, % (m/n)						
<2mg/kg	25.0 (4/16)	90.7 (39/43)	50.0 (1/2)	72.1 (44/61)	77.8 (7/9)	72.9 (51/70)
2–<4mg/kg	81.8 (18/22)	78.3 (65/83)	83.3 (15/18)	79.7 (98/123)	83.3 (20/24)	80.3 (118/147)
4–<8mg/kg		81.0 (17/21)	87.5 (7/8)	82.8 (24/29)	100 (4/4)	84.9 (28/33)
>8mg/kg		0 (0/1)	100 (3/3)	75.0 (3/4)		75.0 (3/4)
Missing	100 (4/4)	61.9 (13/21)	100 (1/1)	69.2 (18/26)	100 (5/5)	74.2 (23/31)
Serious adverse events, % (m/n)						
<2mg/kg	0 (0/16)	39.5 (17/43)	0 (0/2)	27.9 (17/61)	33.3 (3/9)	28.6 (20/70)
2–<4mg/kg	13.6 (3/22)	30.1 (25/83)	33.3 (6/18)	27.6 (34/123)	29.2 (7/24)	27.9 (41/147)
4–<8mg/kg		33.3 (7/21)	25.0 (2/8)	31.0 (9/29)	75.0 (3/4)	36.4 (12/33)
>8mg/kg		0 (0/1)	0 (0/3)	0 (0/4)		0 (0/4)
Missing	0 (0/4)	33.3 (7/21)	100 (1/1)	30.8 (8/26)	40.0 (2/5)	32.3 (10/31)

% values are calculated based on the number of patients within the respective dose category (m/n);

*Other includes atypical CAPS (n=18) and non-CAPS diagnoses (n=24); non-CAPS diagnoses include systemic juvenile idiopathic arthritis, unspecified autoinflammatory syndromes, familial Mediterranean fever, mevalonate kinase deficiency, adult-onset Still's disease, tumour necrosis factor-receptor associated periodic syndrome, Erdheim–Chester disease, Blau syndrome, and granulomatosis with polyangiitis.

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CAPS, cryopyrin-associated periodic syndromes; FCAS, familial cold autoinflammatory syndrome; m, number of patients who reported at least one event; MWS, Muckle–Wells syndrome; n, number of patients within the respective dose category data; NOMID, neonatal-onset multisystem inflammatory disease.

Table S7 Most common adverse events related to canakinumab per investigator assessment

System organ class Preferred term	All CAPS (N=243)	All (N=285)
Any AE, n (IR/ 100 PY) [95% CI]	305 (33.2) [29.6, 37.2]	335 (31.7) [28.4, 35.2]
Infections and infestations	126 (13.7) [11.4, 16.3]	140 (13.2) [11.1, 15.6]
Nasopharyngitis	15 (1.6) [0.9, 2.7]	16 (1.5) [0.9, 2.5]
Lower respiratory tract infection	13 (1.4) [0.8, 2.4]	13 (1.2) [0.7, 2.1]
Urinary tract infection	11 (1.2) [0.6, 2.1]	11 (1.0) [0.5, 1.9]
Tonsillitis	8 (0.9) [0.4, 1.7]	10 (0.9) [0.5, 1.7]
Influenza	9 (1.0) [0.4, 1.9]	9 (0.9) [0.4, 1.6]
Bronchitis	8 (0.9) [0.4, 1.7]	8 (0.8) [0.3, 1.5]
Gastroenteritis	4 (0.4) [0.1, 1.1]	5 (0.5) [0.2, 1.1]
Pneumonia	4 (0.4) [0.1, 1.1]	5 (0.5) [0.2, 1.1]
Ear infection	4 (0.4) [0.1, 1.1]	4 (0.4) [0.1, 1.0]
Rhinitis	4 (0.4) [0.1, 1.1]	4 (0.4) [0.1, 1.0]
Viral infection	2 (0.2) [0, 0.8]	4 (0.4) [0.1, 1.0]
Cellulitis	3 (0.3) [0.1, 1.0]	3 (0.3) [0.1, 0.8]
Herpes zoster	3 (0.3) [0.1, 1.0]	3 (0.3) [0.1, 0.8]
Hordeolum	3 (0.3) [0.1, 1.0]	3 (0.3) [0.1, 0.8]
Laryngitis	3 (0.3) [0.1, 1.0]	3 (0.3) [0.1, 0.8]
Upper respiratory tract infection	1 (0.1) [0.0, 0.6]	3 (0.3) [0.1, 0.8]
General disorders and **administration site conditions**	33 (3.6) [2.5, 5.0]	37 (3.5) [2.5, 4.8]
Fatigue	5 (0.5) [0.2, 1.3]	6 (0.6) [0.2, 1.2]
Pyrexia	5 (0.5) [0.2, 1.3]	5 (0.5) [0.2, 1.1]

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System organ class Preferred term	All CAPS (N=243)	All (N=285)
Vaccination site inflammation	4 (0.4) (0.1, 1.1]	5 (0.5) [0.2, 1.1]
Condition aggravated	3 (0.3) [0.1, 1.0]	3 (0.3) [0.1, 0.8]
Injection site reaction	3 (0.3) [0.1, 1.0]	3 (0.3) [0.1, 0.8]
Malaise	2 (0.2) [0.0, 0.8]	3 (0.3) [0.1, 0.8]
Ear and labyrinth disorders	20 (2.2) [1.3, 3.4]	20 (1.9) [1.2, 2.9]
Vertigo	16 (1.7) [1.0, 2.8]	16 (1.5) [0.9, 2.5]
Gastrointestinal disorders	18 (2.0) [1.2, 3.1]	20 (1.9) [1.2, 2.9]
Abdominal pain upper	5 (0.5) [0.2, 1.3]	5 (0.5) [0.2, 1.1]
Diarrhea	4 (0.4) [0.1, 1.1]	4 (0.4) [0.1, 1.0]
Abdominal pain	3 (0.3) [0.1, 1.0]	3 (0.3) [0.1, 0.8)
Skin and subcutaneous tissue disorders	17 (1.9) [1.1, 3.0]	19 (1.8) [1.1, 2.8]
Rash	3 (0.3) [0.1, 1.0]	4 (0.4) [0.1, 1.0]
Investigations	17 (1.9) [1.1, 3.0]	17 (1.6) [0.9, 2.6]
Weight increased	8 (0.9) [0.4, 1.7]	8 (0.8) [0.3, 1.5]
Injury, poisoning and procedural complications	16 (1.7) [1.0, 2.8]	16 (1.5) [0.9, 2.5]
Vaccination complication	4 (0.4) [0.1, 1.1]	4 (0.4) [0.1, 1.0]
Procedural headache	3 (0.3) [0.1, 1.0]	3 (0.3) [0.1, 0.8]
Procedural nausea	3 (0.3) [0.1, 1.0]	3 (0.3) [0.1, 0.8]
Nervous system disorders	16 (1.7) [1.0, 2.8]	16 (1.5) [0.9, 2.5]
Headache	7 (0.8) [0.3, 1.6]	7 (0.7) [0.3, 1.4]
Syncope	3 (0.3) [0.1, 1.0]	3 (0.3) [0.1, 0.8]

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System organ class Preferred term	All CAPS (N=243)	All (N=285)
Respiratory, thoracic and mediastinal disorders	13 (1.4) [0.8, 2.4]	14 (1.3) [0.7, 2.2]
Cough	5 (0.5) [0.2, 1.3]	5 (0.5) [0.2, 1.1]
Oropharyngeal pain	4 (0.4) [0.1, 1.1]	5 (0.5) [0.2, 1.1]
Eye disorders	7 (0.8) [0.3, 1.6]	8 (0.8) [0.3, 1.5]

Listed are study emergent events starting after baseline with an absolute frequency of ≥5 events per system organ class and ≥ 3 events per preferred term in the all registry patients group.

AE, adverse event; CAPS, cryopyrin-associated periodic syndromes; CI, confidence interval; IR, incidence rate; n, number of events; PY, patient-years.

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Table S8 Serious adverse events by preferred term by patient group (n=1 in all registry patients)

Preferred term n (IR/ 100 PY) (95% CI)	FCAS (n=42)	MWS (n=169)	NOMID (n=32)	All CAPS (n=243)	Other* (n=42)	All (n=285)
All events	4 (2.6) [0.7, 6.6]	100 (15.4) [12.6, 18.8]	24 (21.1) [13.5, 31.4]	128 (14.0) [11.6,16.6]	27 (19.3) [12.7, 28.1]	155 (14.7) [12.4, 17.2]
Anaemia	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Abdominal pain upper	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.00, 0.5]
Abscess limb	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Acute respiratory distress syndrome	0 [0.0, 2.4]	0 [0.0, 0.6]	0 [0.0, 3.2]	0 [0.0, 0.4]	1 (0.7) [0.0, 4.0]	1 (0.1) [0.0, 0.5]
Adenocarcinoma	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Appendicitis	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Arthralgia	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Autoimmune hepatitis	0 [0.0, 2.4]	0 [0.0, 0.6]	0 [0.0, 3.2]	0 [0.0, 0.4]	1 (0.7) [0.0, 4.0]	1 (0.1) [0.0, 0.5]
Bacterial tracheitis	0	1 (0.2)	0	1 (0.1) [0.0, 0.6]	0	1 (0.1) [0.0, 0.5]

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Preferred term n (IR/ 100 PY) (95% CI)	FCAS (n=42)	MWS (n=169)	NOMID (n=32)	All CAPS (n=243)	Other* (n=42)	All (n=285)
	[0.0, 2.4]	[0.0, 0.9]	[0.0, 3.2]		[0.0, 2.7]	
Blindness	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Brain mass	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Bursitis	0 [0.0, 2.4]	0 [0.0, 0.6]	0 [0.0, 3.2]	0 [0.0, 0.4]	1 (0.7) [0.0, 4.0]	1 (0.1) [0.0, 0.5]
Cerebral infarction	1 (0.6) [0.0, 3.6]	0 [0.0, 0.6]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Cholecystitis	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Cholestasis	0 [0.0, 2.4]	0 [0.0, 0.6]	0 [0.0, 3.2]	0 [0.0, 0.4]	1 (0.7) [0.0, 4.0]	1 (0.1) [0.0, 0.5]
Chronic sinusitis	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Circulatory collapse	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Conjunctivitis	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]

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Preferred term n (IR/ 100 PY) (95% CI)	FCAS (n=42)	MWS (n=169)	NOMID (n=32)	All CAPS (n=243)	Other* (n=42)	All (n=285)
Constipation	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Coronary artery disease	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Cough	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Deafness	0 [0.0, 2.4]	0 [0.0, 0.6]	1 (0.9) [0.0, 4.9]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Demyelination	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Diabetes mellitus	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Diplopia	0 [0.0, 2.4]	0 [0.0, 0.6]	1 (0.9) [0.0, 4.9]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Diverticulitis	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Drug hypersensitivity	0 [0.0, 2.4]	0 [0.0, 0.6]	0 [0.0, 3.2]	0 [0.0, 0.4]	1 (0.7) [0.0, 4.0]	1 (0.1) [0.0, 0.5]
Dyspnoea	0 [0.0, 2.4]	0 [0.0, 0.6]	0 [0.0, 3.2]	0 [0.0, 0.4]	1 (0.7) [0.0, 4.0]	1 (0.1) [0.0, 0.5]

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Preferred term n (IR/ 100 PY) (95% CI)	FCAS (n=42)	MWS (n=169)	NOMID (n=32)	All CAPS (n=243)	Other* (n=42)	All (n=285)
Endometriosis	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Enterocolitis	0 [0.0, 2.4]	0 [0.0, 0.6]	0 [0.0, 3.2]	0 [0.0, 0.4]	1 (0.7) [0.0, 4.0]	1 (0.1) [0.0, 0.5]
Epilepsy	0 [0.0, 2.4]	0 [0.0, 0.6]	1 (0.9) [0.0, 4.9]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Epstein-Barr virus infection	0 [0.0, 2.4]	0 [0.0, 0.6]	0 [0.0, 3.2]	0 [0.0, 0.4]	1 (0.7) [0.0, 4.0]	1 (0.1) [0.0, 0.5]
Erysipelas	0 [0.0, 2.4]	0 [0.0, 0.6]	1 (0.9) [0.0, 4.9]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Facial bone fracture	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Familial Mediterranean fever	0 [0.0, 2.4]	0 [0.0, 0.6]	0 [0.0, 3.2]	0 [0.0, 0.4]	1 (0.7) [0.0, 4.0]	1 (0.1) [0.0, 0.5]
Femur fracture	0 [0.0, 2.4]	0 [0.0, 0.6]	0 [0.0, 3.2]	0 [0.0, 0.4]	1 (0.7) [0.0, 4.0]	1 (0.1) [0.0, 0.5]
Gastroenteritis	0 [0.0, 2.4]	0 [0.0, 0.6]	0 [0.0, 3.2]	0 [0.0, 0.4]	1 (0.7) [0.0, 4.0]	1 (0.1) [0.0, 0.5]
Gastroenteritis rotavirus	0 [0.0, 2.4]	0 [0.0, 0.6]	0 [0.0, 3.2]	0 [0.0, 0.4]	1 (0.7) [0.0, 4.0]	1 (0.1) [0.0, 0.5]

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Preferred term n (IR/ 100 PY) (95% CI)	FCAS (n=42)	MWS (n=169)	NOMID (n=32)	All CAPS (n=243)	Other* (n=42)	All (n=285)
Gastrointestinal neoplasm	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Gastrointestinal toxicity	0 [0.0, 2.4]	0 [0.0, 0.6]	0 [0.0, 3.2]	0 [0.0, 0.4]	1 (0.7) [0.0, 4.0]	1 (0.1) [0.0, 0.5]
Gastrooesophageal reflux disease	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Haemoglobin decreased	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Hepatitis	0 [0.0, 2.4]	0 [0.0, 0.6]	0 [0.0, 3.2]	0 [0.0, 0.4]	1 (0.7) [0.0, 4.0]	1 (0.1) [0.0, 0.5]
Herpes zoster	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Hyperhidrosis	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Impaired healing	0 [0.0, 2.4]	0 [0.0, 0.6]	1 (0.9) [0.0, 4.9]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Infection susceptibility increased	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Influenza	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]

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Preferred term n (IR/ 100 PY) (95% CI)	FCAS (n=42)	MWS (n=169)	NOMID (n=32)	All CAPS (n=243)	Other* (n=42)	All (n=285)
Inguinal hernia	0 [0.0, 2.4]	0 [0.0, 0.6]	0 [0.0, 3.2]	0 [0.0, 0.4]	1 (0.7) [0.0, 4.0]	1 (0.1) [0.0, 0.5]
Intervertebral disc protrusion	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Localised oedema	0 [0.0, 2.4]	0 [0.0, 0.6]	0 [0.0, 3.2]	0 [0.0, 0.4]	1 (0.7) [0.0, 4.0]	1 (0.1) [0.0, 0.5]
Lumbar spinal stenosis	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Lymphadenopathy	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Malaise	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Meningitis aseptic	0 [0.0, 2.4]	0 [0.0, 0.6]	1 (0.9) [0.0, 4.9]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Meningitis bacterial	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Mitral valve incompetence	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Myalgia	0 [0.0, 2.4]	0 [0.0, 0.6]	0 [0.0, 3.2]	0 [0.0, 0.4]	1 (0.7) [0.0, 4.0]	1 (0.1) [0.0, 0.5]

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Preferred term n (IR/ 100 PY) (95% CI)	FCAS (n=42)	MWS (n=169)	NOMID (n=32)	All CAPS (n=243)	Other* (n=42)	All (n=285)
Nervous system disorder	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Neurilemmoma benign	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Oral herpes	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Overdose	1 (0.6) [0.0, 3.6]	0 [0.0, 0.6]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Parvovirus B19 infection	0 [0.0, 2.4]	0 [0.0, 0.6]	0 [0.0, 3.2]	0 [0.0, 0.4]	1 (0.7) [0.0, 4.0]	1 (0.1) [0.0, 0.5]
Pericardial effusion	0 [0.0, 2.4]	0 [0.0, 0.6]	0 [0.0, 3.2]	0 [0.0, 0.4]	1 (0.7) [0.0, 4.0]	1 (0.1) [0.0, 0.5]
Periorbital cellulitis	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Peripheral arterial occlusive disease	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Pharyngitis	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Postoperative wound infection	0 [0.0, 2.4]	0 [0.0, 0.6]	0 [0.0, 3.2]	0 [0.0, 0.4]	1 (0.7) [0.0, 4.0]	1 (0.1) [0.0, 0.5]

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Preferred term n (IR/ 100 PY) (95% CI)	FCAS (n=42)	MWS (n=169)	NOMID (n=32)	All CAPS (n=243)	Other* (n=42)	All (n=285)
Post procedural haemorrhage	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Pregnancy	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Prostate cancer	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Radius fracture	1 (0.6) [0.0, 3.6]	0 [0.0, 0.6]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Rash	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Rash generalised	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Rib fracture	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Seizure	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Subcutaneous abscess	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Sudden hearing loss	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]

Preferred term n (IR/ 100 PY) (95% CI)	FCAS (n=42)	MWS (n=169)	NOMID (n=32)	All CAPS (n=243)	Other* (n=42)	All (n=285)
Syncope	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Synovial cyst	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Upper respiratory tract infection	0 [0.0, 2.4]	0 [0.0, 0.6]	0 [0.0, 3.2]	0 [0.0, 0.4]	1 (0.7) [0.0, 4.0]	1 (0.1) [0.0, 0.5]
Uterine leiomyoma	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Vaccination complication	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Vaccination site cellulitis	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]
Ventricular tachycardia	0 [0.0, 2.4]	0 [0.0, 0.6]	0 [0.0, 3.2]	0 [0.0, 0.4]	1 (0.7) [0.0, 4.0]	1 (0.1) [0.0, 0.5]
Vomiting	0 [0.0, 2.4]	0 [0.0, 0.6]	0 [0.0, 3.2]	0 [0.0, 0.4]	1 (0.7) [0.0, 4.0]	1 (0.1) [0.0, 0.5]
Wound infection	0 [0.0, 2.4]	1 (0.2) [0.0, 0.9]	0 [0.0, 3.2]	1 (0.1) [0.0, 0.6]	0 [0.0, 2.7]	1 (0.1) [0.0, 0.5]

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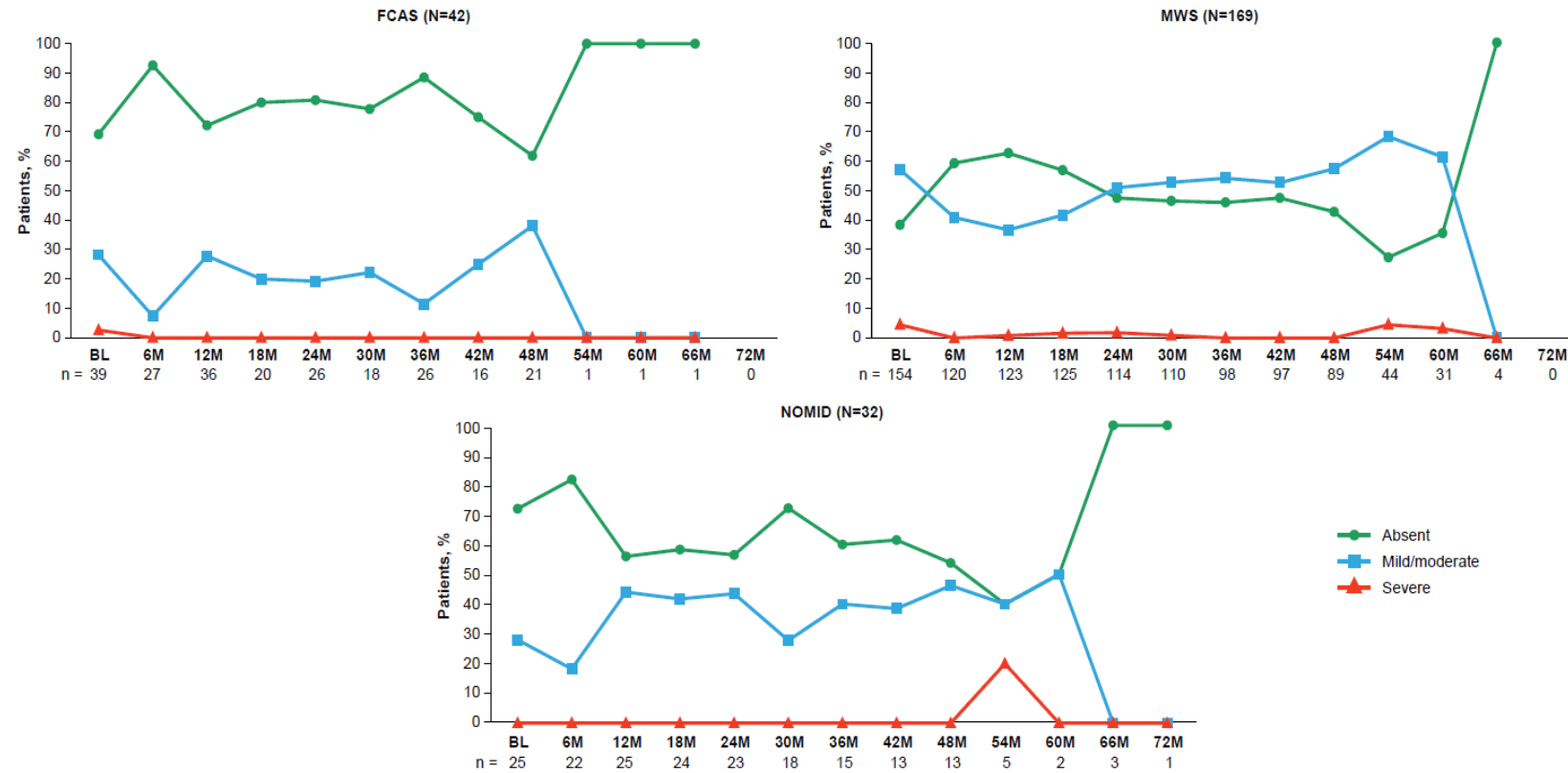| Preferred term n (IR/ 100 PY) (95% CI)	FCAS (n=42)	MWS (n=169)	NOMID (n=32)	All CAPS (n=243)	Other* (n=42)	All (n=285)

Number of events ≥2 in all registry patients are presented in **Table 2** of the manuscript

*Other includes atypical CAPS (n=18) and non-CAPS diagnoses (n=24); non-CAPS diagnoses include systemic juvenile idiopathic arthritis, unspecified autoinflammatory syndromes, familial Mediterranean fever, mevalonate kinase deficiency, adult-onset Still's disease, tumour necrosis factor-receptor associated periodic syndrome, Erdheim–Chester disease, Blau syndrome, and granulomatosis with polyangiitis.
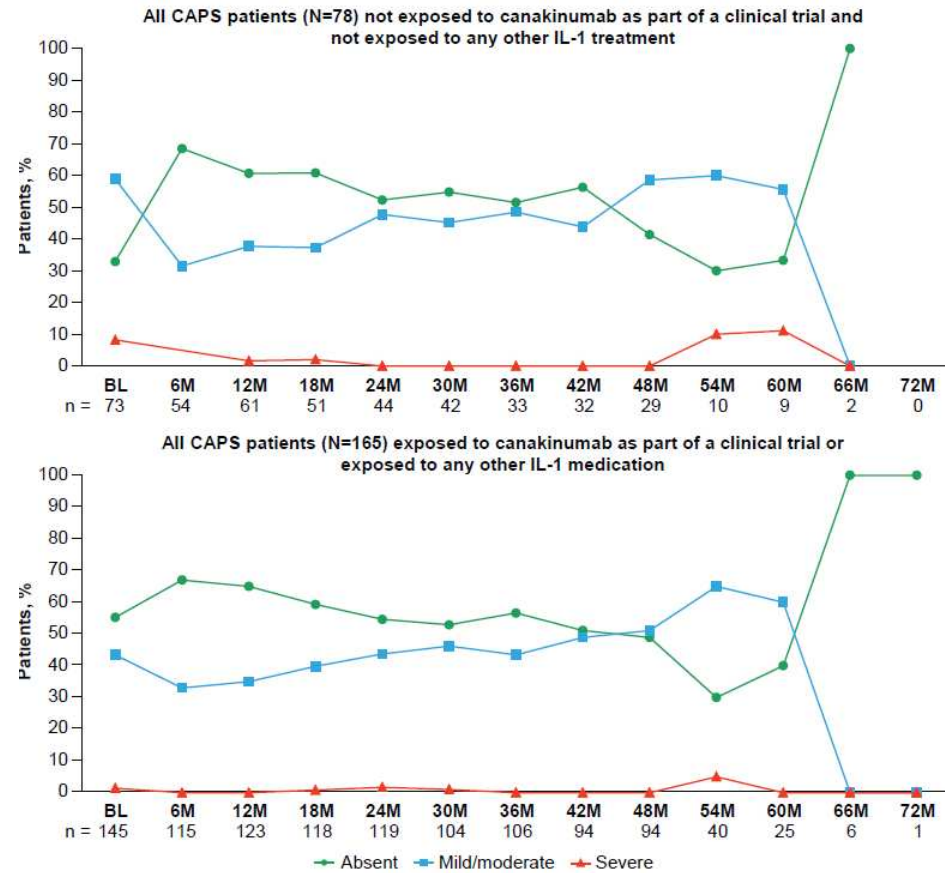
CAPS, cryopyrin-associated periodic syndromes; CI, confidence interval; FCAS, familial cold autoinflammatory syndrome; IR, incidence rate; MWS, Muckle–Wells syndrome; n, number of events, NOMID, neonatal-onset multisystem inflammatory disease; PY, patient-years.

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Figure S1 Physician's Global Assessment of autoinflammatory disease activity and CRP/SAA levels over time
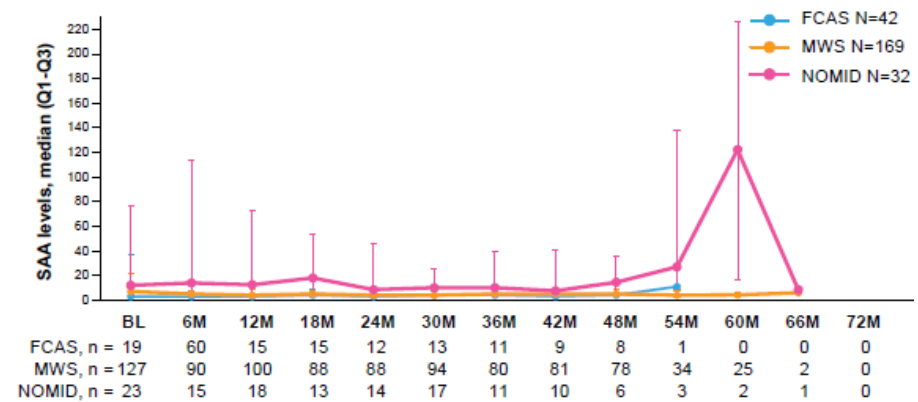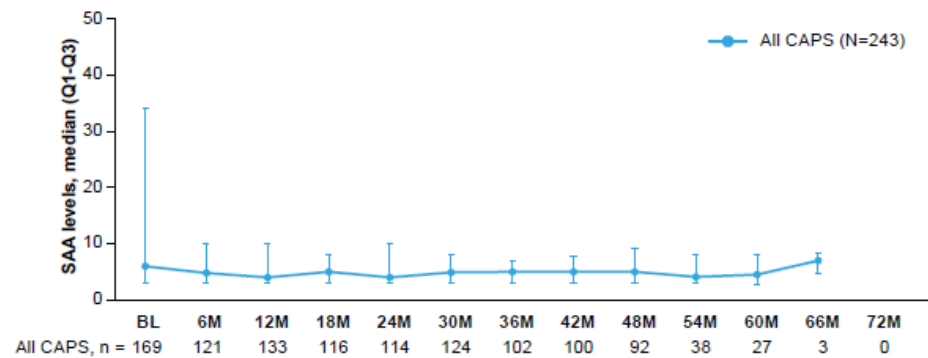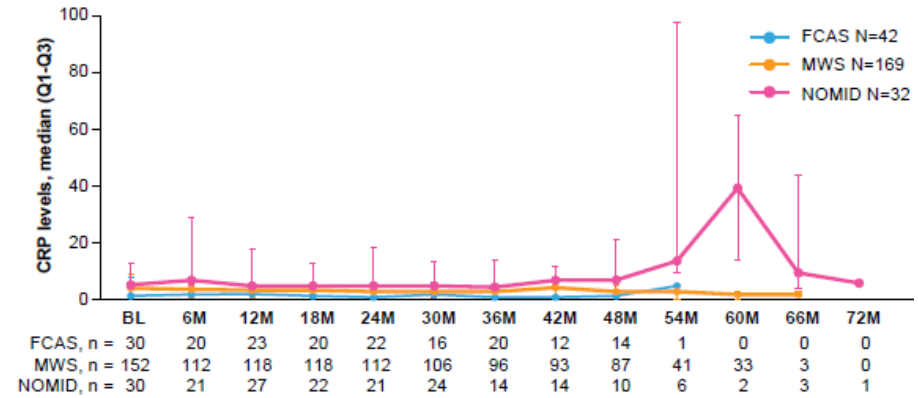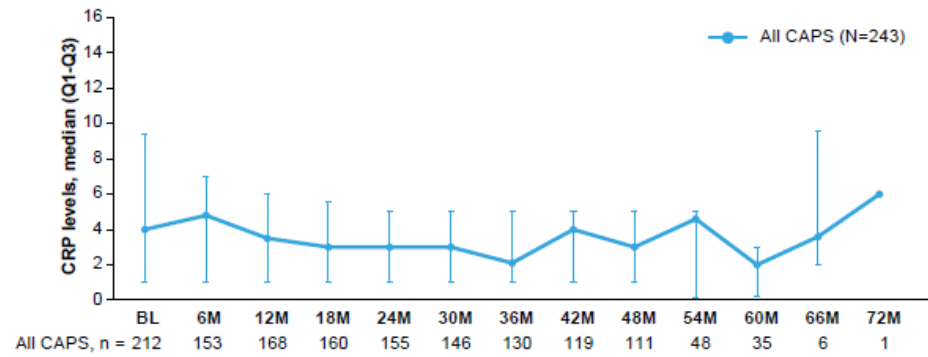
A. CAPS phenotypes

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B. Exposure to anti–IL-1 treatment[*]

All CAPS patients (N=78) not exposed to canakinumab as part of a clinical trial and not exposed to any other IL-1 treatment

	BL	6M	12M	18M	24M	30M	36M	42M	48M	54M	60M	66M	72M
n =	73	54	61	51	44	42	33	32	29	10	9	2	0

All CAPS patients (N=165) exposed to canakinumab as part of a clinical trial or exposed to any other IL-1 medication

	BL	6M	12M	18M	24M	30M	36M	42M	48M	54M	60M	66M	72M
n =	145	115	123	118	119	104	106	94	94	40	25	6	1

Absent — Mild/moderate — Severe

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C. CRP and SAA levels over time

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Supplemental material

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RMD Open

Panel A shows the PGA over time in FCAS, MWS or NOMID patients

Panel B shows PGA over time in All CAPS patients with or without exposure to anti–IL-1 treatment (including canakinumab) prior to enrolment

Panel C shows the CRP and SAA levels over time in ALL CAPS and 'Other' patients group

Percentages are based on the number of available patients at the respective time point

*Patients not exposed to canakinumab as part of a clinical trial and not exposed to any other IL-1 treatment might have started to use marketed canakinumab several weeks before the beginning of the registry.

N, number of evaluable patients; n, number of patients available for assessment at each time point; vertical bars represent Q1 and Q3

BL, baseline; CAPS, cryopyrin-associated periodic syndromes; CRP, C-reactive protein; FCAS, familial cold autoinflammatory syndrome; IL, interleukin; M, months; MWS, Muckle–Wells syndrome; N, number of evaluable patients; n, number of patients available for assessment at each time point; NOMID, neonatal-onset multisystem inflammatory disease; PGA, Physician's Global Assessment; Q, quartile; SAA, serum amyloid A.

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