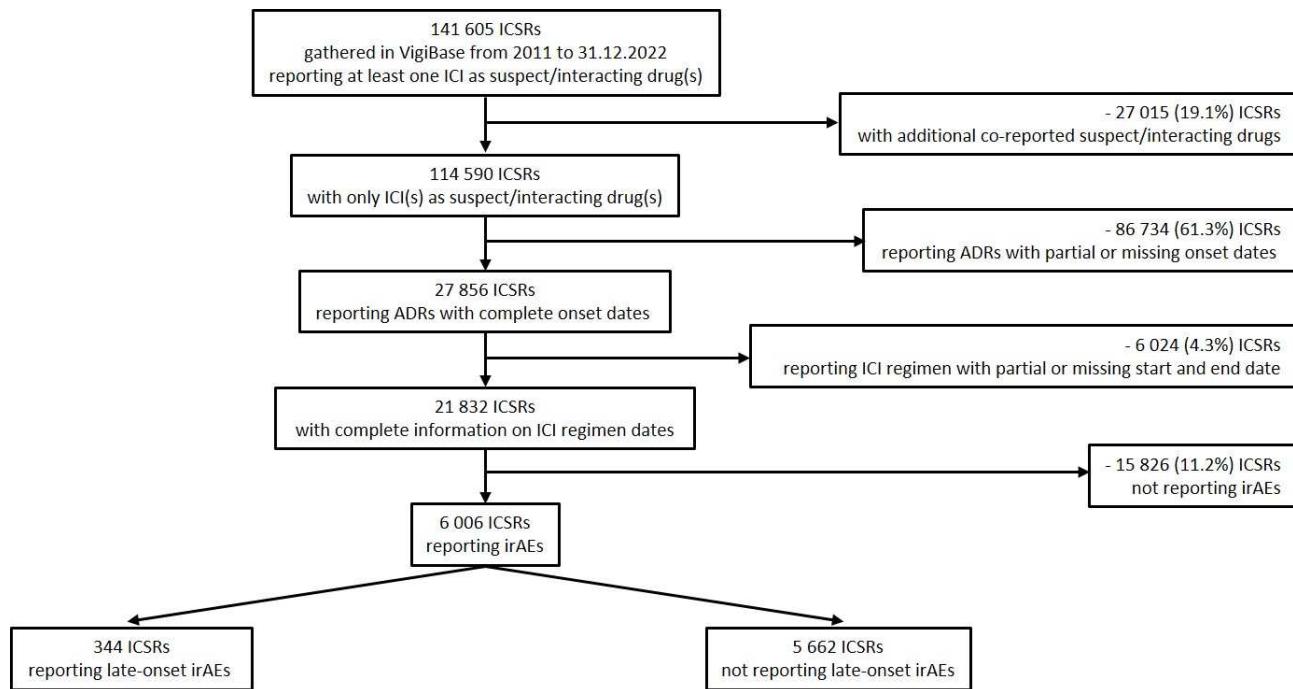


**Supplementary Figure 1** Flowchart summarising the selection of individual case safety reports included in the study population



*Abbreviations:* ICSRs, individual case safety reports; ICI, immune checkpoint inhibitor; ADRs, adverse drug reactions; irAEs, immune-related adverse events

**Supplementary Table 1** List of events containing or ending with '-itis' considered for the selection of immune-related adverse events associated with ICI treatment based on a consensus among authors, comprising clinical pharmacologists

<b>Preferred terms (according to MedDRA version 26.0)</b>
Acrodermatitis enteropathica
Acute haemorrhagic ulcerative colitis
Acute interstitial pneumonitis
Adrenalitis
Allergic colitis
Alveolitis
Angular cheilitis
Appendicitis
Atrophic vulvovaginitis
Blepharitis
Bronchiolitis
Bursitis
Cellulitis
Cheilitis
Cholangitis
Cholecystitis
Cholecystitis chronic
Chorioretinitis
Chronic hepatitis
Colitis ischaemic
Conjunctivitis
Conjunctivitis allergic
Cystitis haemorrhagic
Cystitis noninfective
Dermatitis acneiform
Dermatitis allergic
Dermatitis exfoliative
Dermatitis exfoliative generalised
Dermatitis psoriasiform
Dermo-hypodermitis
Diverticulitis
Duodenitis
Encephalitis toxic
Enterocolitis haemorrhagic
Eosinophilic bronchitis
Eosinophilic colitis

Folliculitis  
Gastritis  
Gastritis erosive  
Gastritis haemorrhagic  
Gastroenteritis  
Gastroenteritis eosinophilic  
Gingivitis  
Glossitis  
Granulomatous pneumonitis  
Haemorrhagic erosive gastritis  
Hand dermatitis  
Hepatitis acute  
Hepatitis cholestatic  
Hepatitis fulminant  
Hepatitis toxic  
Hidradenitis  
Hypersensitivity pneumonitis  
Hypophysitis  
Iridocyclitis  
Iritis  
Keratitis  
Keratouveitis  
Lymphadenitis  
Lymphangitis  
Meningitis  
Meningitis aseptic  
Meningoradiculitis  
Mesenteric panniculitis  
Nasopharyngitis  
Necrotising colitis  
Necrotising myositis  
Nephritis allergic  
Neurodermatitis  
Noninfective gingivitis  
Oedematous pancreatitis  
Oesophagitis  
Oligoarthritis  
Orbital myositis  
Orchitis  
Osteitis deformans

Osteoarthritis  
Osteomyelitis  
Pachymeningitis  
Pancreatitis acute  
Pancreatitis necrotising  
Panniculitis  
Papillitis  
Parotitis  
Periarthritis  
Pericarditis constrictive  
Periostitis  
Plantar fasciitis  
Pleuropericarditis  
Pneumonitis  
Polyarthritis  
Proctitis  
Pseudomembranous colitis  
Rhinitis  
Rhinitis allergic  
Scrotal dermatitis  
Seborhoeic dermatitis  
Seronegative arthritis  
Serositis  
Sialoadenitis  
Spinal osteoarthritis  
Synovitis  
Tendonitis  
Tenosynovitis  
Thrombophlebitis  
Thrombophlebitis migrans  
Thyroiditis acute  
Thyroiditis subacute  
Tubulointerstitial nephritis  
Ulcerative gastritis  
Vestibular neuritis  
Vulvitis

*Abbreviations:* MedDRA, Medical Dictionary for Regulatory Activities

**Supplementary Table 2** Spectrum of the clinical presentations of late-onset immune-related adverse events by organ toxicity

Organ toxicity	Clinical presentation (MedDRA preferred terms)	N
<b>Endocrine</b>	thyroiditis	45
	diabetes mellitus	20
	hypophysitis	17
	adrenalitis	2
<b>Gastrointestinal</b>	colitis	30
	pancreatitis	15
	enterocolitis	10
	gastritis	9
	cholangitis	2
	cholecystitis	2
	diverticulitis	2
	duodenitis	1
	oesophagitis	1
<b>Respiratory</b>	pneumonitis	37
	interstitial lung disease	25
	nasopharyngitis	4
	rhinitis	1
<b>Skin</b>	vitiligo	19
	pemphigoid	7
	dermatitis	4
	psoriasis	4
	panniculitis	2
	cellulitis	2
	cutaneous lupus	2
	dermo-hypodermitis	1
	erythema multiforme	1
	erythema nodosum	1
	folliculitis	1
<b>Neurologic</b>	lichen planus	1
	neuropathy	18
	myelitis	3
	encephalitis	2
	encephalopathy	2
	myastenia	2

	neuritis	1
<b>Hepatic</b>	hepatitis	23
<b>Musculoskeletal</b>	arthritis polymyalgia rheumatica fasciitis myositis osteitis deformans synovitis tendonitis	11 4 2 2 1 1 1
<b>Eye</b>	uveitis conjunctivitis iritocyclitis iritis keratitis	4 2 1 1 1
<b>Renal</b>	nephritis cystitis	8 1
<b>Cardiac</b>	myocarditis pericarditis	5 3
<b>Other</b>	immune-mediated adverse reaction anti-actin antibody positive anti-neutrophil cytoplasmic antibody positive autoinflammatory disease serositis smooth muscle antibody positive	2 1 1 1 1 1
<b>Blood</b>	anaemia thrombocytopenia neutropenia	2 2 1
<b>Vascular</b>	vasculitis lymphagitis	4 1
<b>Immune</b>	sarcoidosis Sjogren's syndrome thrombocytopenic purpura	2 1 1

Abbreviations: MedDRA, Medical Dictionary for Regulatory Activities