

Provision of Publicly Available FAERs Data for Remicade® (Infliximab)

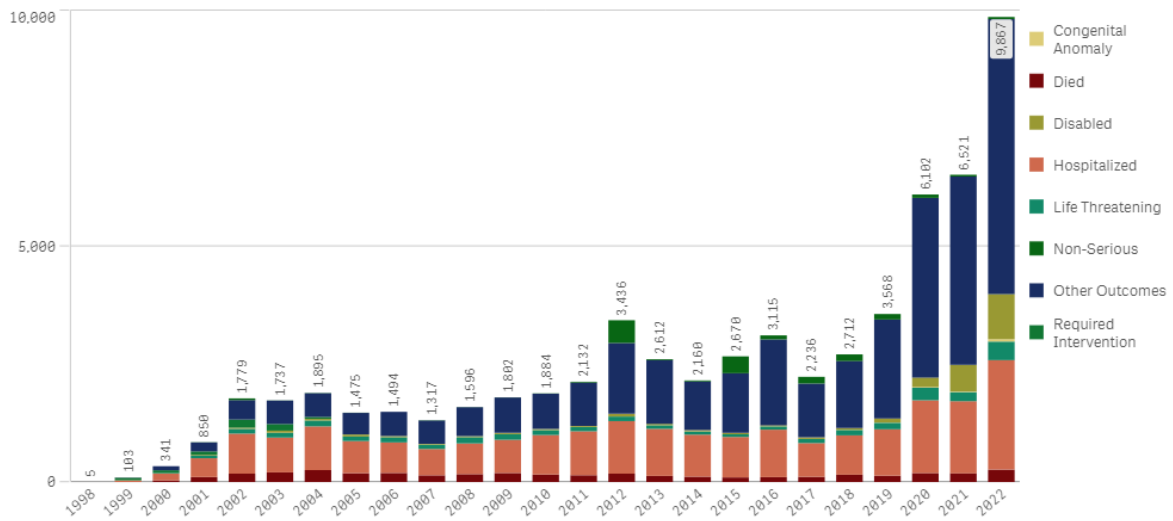
You are accessing this document as you are taking part in the Veradigm Adverse Event Deep-Dive Program, a GSK sponsored pilot program which aims to facilitate and evaluate a bi-directional communication process with a trusted third party using the Practice Fusion secure messaging system to enhance and streamline post-market drug adverse event data collection and assessment.

The FDA's Adverse Event Reporting System (FDA AERS or FAERs), is a publicly available database which contains more than 28 million deidentified reports of AEs. Information from the FAERs public dashboard has been *pre-filtered to Remicade® (Infliximab) and all infections*, with data as of 30 September 2022.

The information provided below is for **information purposes only**, when using this data, you should be aware that there are a number of limitations, these are described in detail in this document and available on the FAERs public dashboard website. If you have any questions related to Remicade please contact the manufacturer Janssen on 1-800-526-7736.

Pre-filtered to Remicade® (Infliximab) and ALL INFECTIONS, with data as of 30 September 2022.

Outcome counts by Received Year



Case counts by Age Group and Sex

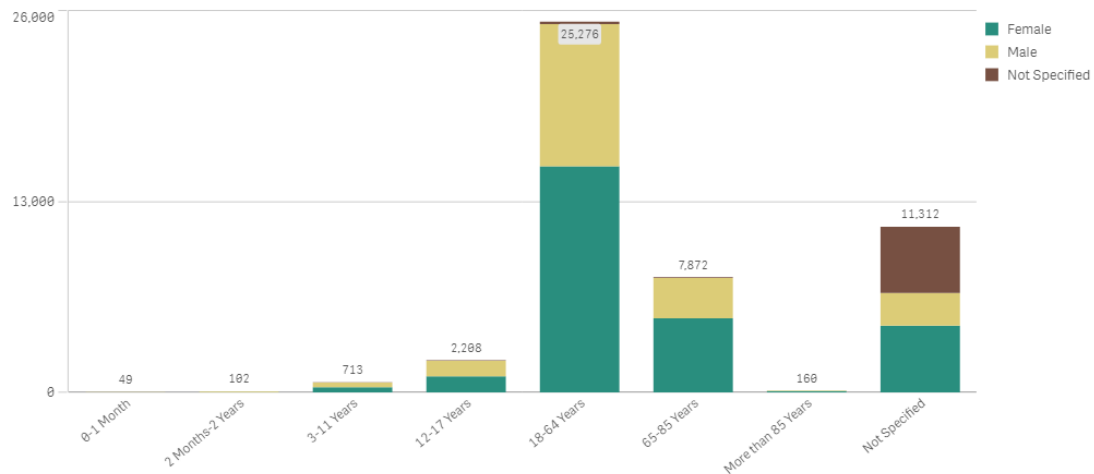


Table of Adverse Events of Infections (n≥10) (Remicade® (Infliximab)) with data as of 30 September 2022

Reaction Term	Count	Reaction Term	Count
Pneumonia	5,758	Visceral Leishmaniasis	33
Infection	4,120	Campylobacter Infection	33
Nasopharyngitis	2,980	Wound Infection Staphylococcal	32
Herpes Zoster	2,495	Pneumonia Klebsiella	32
Sinusitis	2,306	Toxoplasmosis	32
Tuberculosis	2,217	Chlamydial Infection	31
Sepsis	2,035	Pneumonia Mycoplasmal	31
Urinary Tract Infection	1,864	Pericarditis Tuberculous	31
Lower Respiratory Tract Infection	1,735	Vulval Abscess	31
Helicobacter Infection	1,562	Infected Skin Ulcer	30
Covid-19	1,530	Cytomegalovirus Enterocolitis	30
Influenza	1,224	Fungal Oesophagitis	30
Clostridium Difficile Infection	1,148	Bronchiolitis	30
Abscess	1,111	Candida Sepsis	30
Cellulitis	1,086	Abdominal Sepsis	29
Pulmonary Tuberculosis	1,047	Bk Virus Infection	29
Folliculitis	1,030	Infection Susceptibility Increased	29
Bronchitis	989	Psoas Abscess	29
Staphylococcal Infection	953	Otitis Externa	29
Diverticulitis	846	Abdominal Wall Abscess	29
Disseminated Tuberculosis	799	Endocarditis Bacterial	28
Pneumocystis Jirovecii Pneumonia	785	Acinetobacter Infection	28
Upper Respiratory Tract Infection	777	Pseudomonal Sepsis	28
Septic Shock	742	Human Herpesvirus 6 Infection	28
Cytomegalovirus Infection	666	Extradural Abscess	28
Anal Abscess	624	Perineal Abscess	28
Fungal Infection	582	Eye Infection Toxoplasmal	28
Viral Infection	507	Cytomegalovirus Enteritis	28
Ear Infection	468	Endophthalmitis	27
Cystitis	456	Colonic Abscess	27
Localised Infection	438	Enteritis Infectious	27
Histoplasmosis	403	Bacillus Infection	27
Candida Infection	383	Bronchitis Bacterial	27
Osteomyelitis	379	Tuberculosis Of Central Nervous System	27
Bacterial Infection	357	Respiratory Syncytial Virus Infection	26
Wound Infection	352	Oropharyngeal Candidiasis	26
Respiratory Tract Infection	347	Spleen Tuberculosis	26
Gastroenteritis	334	Alpha Haemolytic Streptococcal Infection	26
Post Procedural Infection	326	Large Intestine Infection	26
Skin Infection	319	Salmonella Sepsis	26
Pharyngitis	318	Respiratory Tract Infection Viral	25
Histoplasmosis Disseminated	304	Nosocomial Infection	25
Gastroenteritis Viral	295	Pathogen Resistance	24
Kidney Infection	287	Vulvovaginal Candidiasis	24
Oral Herpes	280	Cellulitis Staphylococcal	24
Pneumonia Legionella	279	Cholecystitis Infective	24
Gastrointestinal Infection	269	Diarrhoea Infectious	24
Arthritis Bacterial	268	Herpes Zoster Disseminated	24
Oral Candidiasis	267	Systemic Mycosis	24
Postoperative Wound Infection	267	Renal Abscess	24
Tooth Abscess	261	Infectious Pleural Effusion	23

Abdominal Abscess	252	Encephalitis Viral	23
Tooth Infection	251	Escherichia Bacteraemia	23
Pharyngitis Streptococcal	247	Whipple'S Disease	23
Epstein-Barr Virus Infection	220	Cerebral Aspergillosis	23
Lymph Node Tuberculosis	220	Immune Reconstitution Inflammatory Syndrome Associated Tuberculosis	23
Peritonitis	214	Acute Sinusitis	22
Subcutaneous Abscess	210	Listeria Encephalitis	22
Bacteraemia	208	Campylobacter Gastroenteritis	22
Appendicitis	202	Infection Parasitic	22
Conjunctivitis	201	Cryptosporidiosis Infection	22
Streptococcal Infection	201	Sialoadenitis	22
Listeriosis	201	Retroperitoneal Abscess	22
Pyelonephritis	198	Vaginal Abscess	22
Device Related Infection	197	Cutaneous Tuberculosis	22
Onychomycosis	192	Herpes Zoster Oticus	22
Escherichia Infection	187	Blastomycosis	21
Bronchopulmonary Aspergillosis	186	Proteus Infection	21
Herpes Simplex	183	Gastrointestinal Bacterial Infection	21
Meningitis	181	Nail Infection	21
Staphylococcal Sepsis	178	Rhinovirus Infection	21
Aspergillus Infection	177	Parotitis	21
Abscess Limb	177	Fungal Sepsis	21
Urosepsis	176	Aspergilloma	21
Eye Infection	175	Pertussis	20
Laryngitis	175	Neutropenic Sepsis	20
Clostridium Difficile Colitis	174	Molluscum Contagiosum	20
Cytomegalovirus Colitis	173	Uterine Infection	20
Pneumonia Viral	173	Parvovirus Infection	20
Tonsillitis	172	Cytomegalovirus Gastrointestinal Infection	20
Furuncle	170	Acarodermatitis	20
Rectal Abscess	168	Respiratory Tract Infection Fungal	20
Varicella	163	Abscess Bacterial	20
Mycobacterium Avium Complex Infection	160	Injection Site Infection	19
Herpes Virus Infection	160	Periodontitis	19
Encephalitis	158	Otitis Media Acute	19
Peritoneal Tuberculosis	157	H1n1 Influenza	19
Coccidioidomycosis	154	Serratia Infection	19
Pseudomonas Infection	153	Citrobacter Infection	19
Meningitis Listeria	153	Enterovirus Infection	19
Abscess Intestinal	148	Gastrointestinal Viral Infection	19
Salmonellosis	141	Joint Tuberculosis	19
Pneumonia Bacterial	138	Disseminated Aspergillosis	19
Clostridial Infection	138	Catheter Site Infection	18
Infectious Mononucleosis	138	Pulpitis Dental	18
Latent Tuberculosis	136	Tinea Infection	18
Opportunistic Infection	134	Mastoiditis	18
Mycobacterial Infection	133	Gastrointestinal Candidiasis	18
Rhinitis	132	Viraemia	18
Tuberculous Pleurisy	132	Human Herpesvirus 8 Infection	18
Oesophageal Candidiasis	131	Pelvic Inflammatory Disease	17
Pneumonia Fungal	131	Pyuria	17
Rash Pustular	130	Jc Virus Infection	17

Chronic Sinusitis	119	Bacterial Vulvovaginitis	17
Vaginal Infection	116	Cerebral Toxoplasmosis	17
Perirectal Abscess	114	Strongyloidiasis	17
Pneumonia Aspiration	112	Rotavirus Infection	17
Mycobacterium Marinum Infection	111	Overgrowth Bacterial	17
Retinitis	111	Actinomycosis	17
Atypical Mycobacterial Infection	107	Epiglottitis	17
Nocardiosis	104	Infected Bite	17
Pneumocystis Jirovecii Infection	104	Herpes Oesophagitis	17
Ophthalmic Herpes Zoster	103	Pulmonary Sepsis	17
Purulent Discharge	101	Scrotal Abscess	17
Liver Abscess	100	Septic Arthritis Staphylococcal	17
Arthritis Infective	99	Tuberculosis Liver	17
Erysipelas	99	Mycobacterium Kansasii Infection	17
Legionella Infection	98	Anal Fistula Infection	17
Suspected Covid-19	97	Pulmonary Nocardiosis	17
Pelvic Abscess	96	Human Polyomavirus Infection	16
Gingivitis	93	Septic Embolus	16
Enterococcal Infection	92	Tracheobronchitis	16
Escherichia Urinary Tract Infection	92	Tinea Pedis	16
Endocarditis	91	Prostate Infection	16
Covid-19 Pneumonia	91	Salmonella Bacteraemia	16
Progressive Multifocal Leukoencephalopathy	87	Wound Infection Bacterial	16
Klebsiella Infection	87	Cytomegalovirus Hepatitis	16
Pneumonia Cryptococcal	86	Cat Scratch Disease	15
Viral Upper Respiratory Tract Infection	84	Bacterial Vaginosis	15
Lung Abscess	83	Skin Bacterial Infection	15
Hepatitis B	81	Pneumonia Necrotising	15
Varicella Zoster Virus Infection	81	Meningitis Herpes	15
Brain Abscess	78	Root Canal Infection	15
Tuberculosis Gastrointestinal	73	Cystitis Escherichia	15
Extrapulmonary Tuberculosis	73	Gastrointestinal Fungal Infection	15
Adenovirus Infection	72	Lower Respiratory Tract Infection Viral	15
Meningitis Tuberculous	71	Polyomavirus-Associated Nephropathy	14
Mastitis	71	Incision Site Abscess	14
Bacterial Sepsis	71	Body Tinea	14
Vulvovaginal Mycotic Infection	70	Streptococcal Bacteraemia	14
Hepatitis C	69	Orchitis	14
Herpes Ophthalmic	69	Pseudomembranous Colitis	14
Empyema	66	Pneumococcal Sepsis	14
Escherichia Sepsis	66	Osteomyelitis Chronic	14
Impetigo	65	Lower Respiratory Tract Infection Bacterial	14
Purulence	64	Viral Pericarditis	14
Lyme Disease	64	Stoma Site Infection	14
Hepatitis B Reactivation	63	Bacterial Translocation	14
Papilloma Viral Infection	63	Stoma Site Abscess	14
Listeria Sepsis	63	Klebsiella Sepsis	14
Appendicitis Perforated	62	Eye Infection Bacterial	14
Meningitis Aseptic	61	Mycoplasma Infection	14
Gastroenteritis Salmonella	60	Relapsing Fever	14
Hordeolum	59	Pneumonia Influenzal	14

Epstein-Barr Virus Infection Reactivation	59	Leprosy	14
Bursitis Infective	59	Ear Infection Bacterial	14
Pyoderma	58	Mycobacterium Haemophilum Infection	14
Pustule	57	Peritonitis Bacterial	13
Cutaneous Leishmaniasis	57	Muscle Abscess	13
Cytomegalovirus Viraemia	57	Cardiac Infection	13
Beta Haemolytic Streptococcal Infection	56	Syphilis	13
Clostridium Colitis	55	Chorioretinitis	13
Cytomegalovirus Infection Reactivation	55	Gastroenteritis Clostridial	13
Postoperative Abscess	55	Lymphangitis	13
Fungal Skin Infection	54	Enterococcal Bacteraemia	13
Systemic Candida	54	Meningitis Pneumococcal	13
Oral Fungal Infection	54	Herpes Simplex Encephalitis	13
Leishmaniasis	53	Post Procedural Sepsis	13
Otitis Media	53	Omphalitis	13
Pneumonia Staphylococcal	52	Disseminated Cytomegaloviral Infection	13
Infected Cyst	52	Mucocutaneous Leishmaniasis	13
Device Related Sepsis	52	Cutaneous Nocardiosis	13
Lupus Vulgaris	52	Central Nervous System Infection	12
Meningitis Cryptococcal	51	Superinfection Bacterial	12
Epididymitis	51	Infusion Site Infection	12
Infected Fistula	51	Pneumococcal Infection	12
Meningitis Viral	50	Gastroenteritis Rotavirus	12
Atypical Pneumonia	50	Viral Myocarditis	12
Myelitis	50	Hepatitis Viral	12
Superinfection	49	Genitourinary Tract Infection	12
Pneumonia Cytomegaloviral	49	Dysentery	12
Abdominal Infection	49	Spinal Cord Infection	12
Staphylococcal Skin Infection	48	Eczema Infected	12
Streptococcal Sepsis	48	Ear Infection Fungal	12
Intestinal Sepsis	48	Genital Abscess	12
Vascular Device Infection	47	Infestation	12
Intervertebral Discitis	47	Infective Tenosynovitis	12
Groin Abscess	47	Abscess Rupture	12
Pleural Infection	46	Hiv Infection	11
Pneumonia Pseudomonal	46	Infective Aneurysm	11
Bone Tuberculosis	46	Stenotrophomonas Infection	11
Pneumonia Streptococcal	45	Candida Pneumonia	11
Cryptococcosis	45	Cervicitis	11
Labyrinthitis	44	Periumbilical Abscess	11
Genital Herpes	44	Tonsillitis Streptococcal	11
Necrotising Fasciitis	43	Bone Abscess	11
Oral Infection	43	Mycobacterium Fortuitum Infection	11
Sinusitis Bacterial	43	Abscess Neck	11
Pilonidal Disease	43	Disseminated Cryptococcosis	11
Staphylococcal Abscess	42	Gastroenteritis Bacterial	11
Breast Abscess	42	Eye Infection Fungal	11
Pneumonia Pneumococcal	41	Hand-Foot-And-Mouth Disease	11
Staphylococcal Bacteraemia	41	Renal Tuberculosis	11
Infection In An Immunocompromised Host	41	Dermatitis Infected	11

Gastric Infection	41	Acid Fast Bacilli Infection	11
Pyelonephritis Acute	40	Conjunctivitis Bacterial	11
Paronychia	39	Parainfluenzae Virus Infection	10
Meningoencephalitis Herpetic	39	Staphylococcal Osteomyelitis	10
Gastroenteritis Norovirus	39	Pyomyositis	10
Soft Tissue Infection	39	Pharyngitis Bacterial	10
Urinary Tract Infection Bacterial	39	Scarlet Fever	10
Mucormycosis	38	Sinusitis Fungal	10
Infection Reactivation	38	Bacterial Disease Carrier	10
Coronavirus Infection	37	Amniotic Cavity Infection	10
Helicobacter Gastritis	37	Viral Pharyngitis	10
Acute Pulmonary Histoplasmosis	37	Respiratory Moniliasis	10
Mycobacterium Chelonae Infection	37	Epstein-Barr Viraemia	10
Meningitis Bacterial	36	Creutzfeldt-Jakob Disease	10
Dengue Fever	36	Fusarium Infection	10
Abscess Oral	36	Lymphadenitis Bacterial	10
Fungaemia	35	Anal Infection	10
Gangrene	34	Necrotising Fasciitis Streptococcal	10
Haemophilus Infection	34	Endocarditis Staphylococcal	10
Intestinal Tuberculosis	34	Cytomegalovirus Mononucleosis	10
Peritonsillar Abscess	33	Pulmonary Mucormycosis	10
Enterobacter Infection	33		

Limitations of FAERs Data

- **The information retrieved from the FAERS database should not be used to draw any conclusions** regarding the safety of the medicinal products as individual reports do not imply causality of the product. The output is not considered “CDS” and are not intended to be designed, implemented, provided and/or used to influence clinical decisions or as clinical decision support (CDS).
- **FAERs is significantly limited by underreporting:** Despite the significant increases in AE reporting, limitations in the use of FAERS data for post-market surveillance remain. One of the biggest limitations is that not all adverse events are reported. As a spontaneous (i.e., voluntary) reporting system, it's simply not possible for every adverse event to be recorded. A systematic review of underreporting estimates that is 94%⁴. Therefore, the number of reports cannot be interpreted or used in isolation to reach conclusions about the existence, severity, or frequency of the adverse event in association with the drug.
- **Rates of occurrence cannot be established with reports:** FAERs data alone cannot be used to establish rates of events, evaluate a change in event rates over time or compare event rates between drug products and are significantly impacted by the Weber effect which is often summarised by stating that AE reporting peaks at the end of the second year after.
- **FAERs data do not represent all known safety information** for a reported drug product and should be interpreted in the context of other available information when making drug-related or treatment decisions.
- **Information in reports has not been verified:** Safety reports submitted to FDA does not mean that the information included in it has been medically confirmed and does not reflect a conclusion by FDA or the marketing authorisation holder that the information in the report constitutes an admission that the drug caused or contributed to an adverse event.