

Provision of Publicly Available FAERs Data for Humira® (Adalimumab)

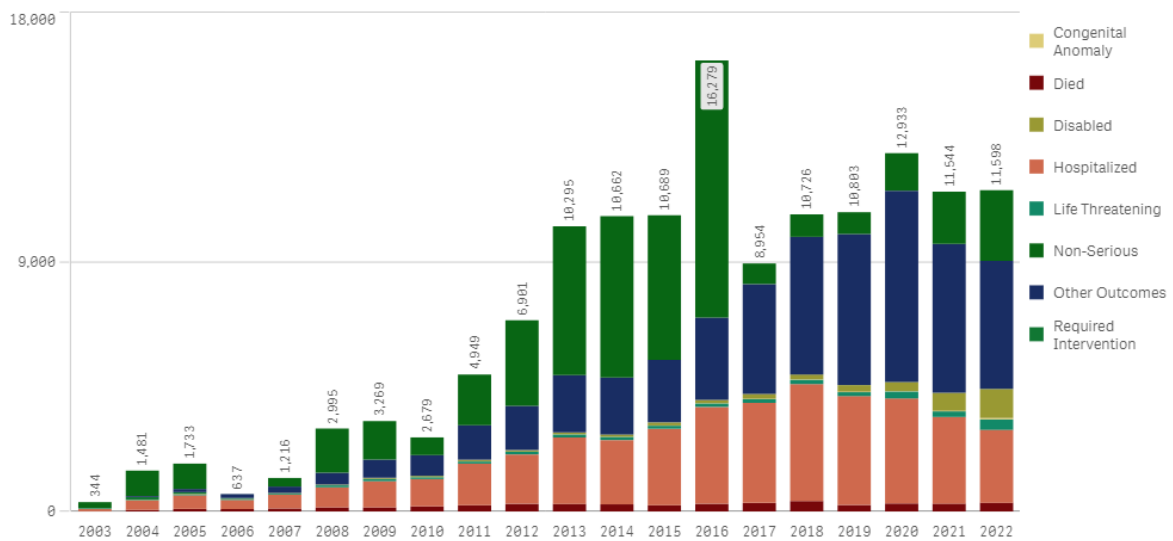
You are accessing this document as you are taking part in the Veradigm Adverse Event Deep-Dive Program, a GSK sponsored pilot program which aims to facilitate and evaluate a bi-directional communication process with a trusted third party using the Practice Fusion secure messaging system to enhance and 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 Humira® (Adalimumab) 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 Humira please contact the manufacturer AbbVie on 1-800-633-9110.

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

Outcome counts by Received Year



Case counts by Age Group and Sex

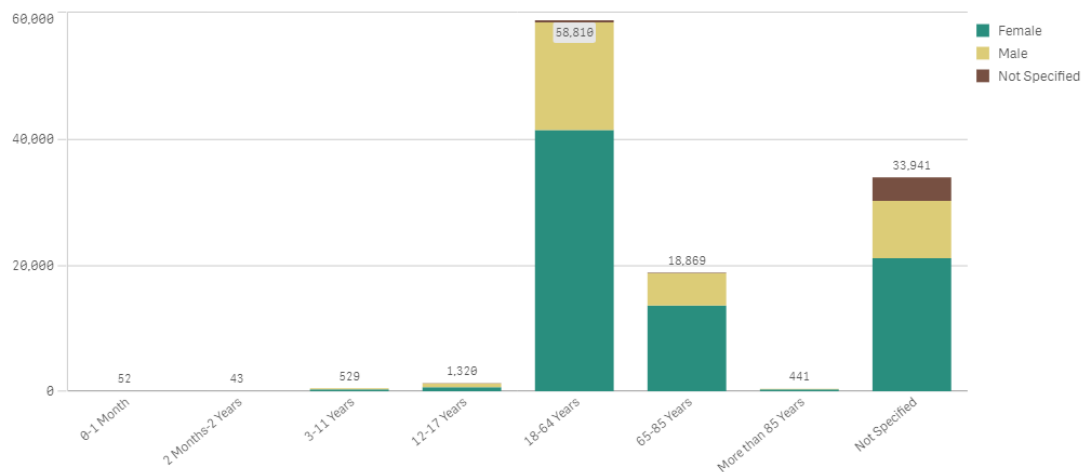


Table of Adverse Events of Infections (Humira® (Adalimumab)) with data as of 30 September 2022

Reaction Term	Count	Reaction Term	Count
Nasopharyngitis	14,935	Hepatitis A	35
Pneumonia	11,907	Uterine Infection	35
Sinusitis	10,122	Epididymitis	35
Infection	9,349	Bone Abscess	35
Urinary Tract Infection	6,913	Perineal Abscess	35
Influenza	5,459	Wound Infection Bacterial	35
Bronchitis	4,979	Haemophilus Infection	34
Herpes Zoster	4,239	Spinal Cord Abscess	34
Covid-19	3,675	Enterobacter Infection	34
Upper Respiratory Tract Infection	3,416	Joint Abscess	34
Sepsis	3,296	Injection Site Abscess	33
Staphylococcal Infection	2,501	Body Tinea	33
Lower Respiratory Tract Infection	2,396	Pneumonia Pseudomonal	33
Cellulitis	2,393	Fungal Oesophagitis	33
Ear Infection	2,094	Groin Infection	33
Localised Infection	1,804	Scrotal Abscess	33
Abscess	1,769	Pneumonia Mycoplasmal	33
Fungal Infection	1,732	Campylobacter Infection	33
Diverticulitis	1,726	Post Procedural Pneumonia	33
Helicobacter Infection	1,692	Hepatitis B Reactivation	32
Cystitis	1,674	Central Nervous System Infection	32
Viral Infection	1,504	Rhinovirus Infection	32
Clostridium Difficile Infection	1,462	Gingival Abscess	32
Tuberculosis	1,285	Toxoplasmosis	32
Folliculitis	1,209	Lymphangitis	32
Kidney Infection	1,126	Infective Exacerbation Of Chronic Obstructive Airways Disease	32
Tooth Infection	1,124	Wound Infection Pseudomonas	32
Respiratory Tract Infection	1,119	Pyuria	31
Pharyngitis Streptococcal	1,106	Pharyngeal Abscess	31
Post Procedural Infection	1,045	Whipple'S Disease	31
Postoperative Wound Infection	1,013	Oropharyngeal Candidiasis	30
Furuncle	996	Abscess Jaw	30
Gastrointestinal Infection	990	Leishmaniasis	30
Oral Herpes	911	Pneumonia Klebsiella	30
Gastroenteritis Viral	898	Parotitis	30
Pharyngitis	893	Atypical Mycobacterial Infection	30
Septic Shock	846	Bronchitis Viral	30
Bacterial Infection	824	Anorectal Infection	30
Tooth Abscess	745	Eye Infection Fungal	30
Wound Infection	737	Hiv Infection	29
Skin Infection	725	Nocardiosis	29
Osteomyelitis	708	Mastoiditis	29
Candida Infection	693	Mycobacterium Marinum Infection	29
Anal Abscess	641	Abscess Bacterial	29
Abscess Intestinal	632	Cryptococcosis	29
Laryngitis	597	Anal Infection	29
Eye Infection	582	Gastrointestinal Fungal Infection	29
Purulent Discharge	544	Molluscum Contagiosum	28
Abdominal Abscess	536	Borrelia Infection	28
Rash Pustular	522	Tinea Cruris	28

Conjunctivitis	508	Infection Reactivation	28
Tonsillitis	455	Overgrowth Bacterial	27
Oral Candidiasis	440	Bacterial Disease Carrier	27
Arthritis Infective	431	Fungal Sepsis	27
Onychomycosis	410	Eye Infection Bacterial	27
Rhinitis	409	Septic Arthritis Staphylococcal	27
Appendicitis	391	Infection Transmission Via Personal Contact	27
Abscess Limb	374	Sputum Purulent	27
Peritonitis	364	Herpes Simplex Oesophagitis	27
Arthritis Bacterial	364	Pelvic Infection	26
Subcutaneous Abscess	364	Systemic Candida	26
Gastroenteritis	356	Ear Infection Fungal	26
Device Related Infection	350	Medical Device Site Joint Infection	26
Streptococcal Infection	342	Asymptomatic Covid-19	26
Pulmonary Tuberculosis	331	Meningitis Tuberculous	25
Gingivitis	326	Meningoencephalitis Herpetic	25
Gastric Infection	325	Meningitis Listeria	25
Rectal Abscess	305	Gastroenteritis Escherichia Coli	25
Escherichia Infection	303	Neutropenic Sepsis	24
Pustule	301	Vulvovaginal Candidiasis	24
Disseminated Tuberculosis	295	Haematoma Infection	24
Herpes Virus Infection	295	Respiratory Tract Infection Fungal	24
Purulence	293	Cutaneous Tuberculosis	24
Urosepsis	278	Vestibular Neuritis	24
Fungal Skin Infection	277	Hand-Foot-And-Mouth Disease	24
Suspected Covid-19	277	Anal Fistula Infection	24
Meningitis	266	Splenic Abscess	23
Vulvovaginal Mycotic Infection	257	Cat Scratch Disease	23
Clostridium Difficile Colitis	253	Catheter Site Infection	23
Latent Tuberculosis	243	Endophthalmitis	23
Vaginal Infection	242	Pancreas Infection	23
Lyme Disease	242	Rotavirus Infection	23
Pneumocystis Jirovecii Pneumonia	236	Pneumococcal Sepsis	23
Pneumonia Legionella	233	Lower Respiratory Tract Infection Fungal	23
Pyelonephritis	231	Cryptosporidiosis Infection	23
Hepatitis C	230	Wound Sepsis	23
Herpes Simplex	228	Alveolar Osteitis	22
Pneumonia Viral	227	Eyelid Infection	22
Wound Infection Staphylococcal	222	Ear Lobe Infection	22
Encephalitis	211	Genital Infection Fungal	22
Histoplasmosis	209	Hepatitis E	21
Pneumonia Aspiration	208	Chlamydial Infection	21
Chronic Sinusitis	206	Human Herpesvirus 6 Infection	21
Oral Infection	200	Pseudomembranous Colitis	21
Coronavirus Infection	200	Eye Infection Staphylococcal	21
Oral Fungal Infection	196	Sinusitis Fungal	21
Viral Upper Respiratory Tract Infection	189	Cervicitis	21
Erysipelas	189	Amoebiasis	21
Cytomegalovirus Infection	185	Retroperitoneal Abscess	21
Infectious Mononucleosis	182	Gastrointestinal Bacterial Overgrowth	21
Pneumonia Bacterial	181	Eye Infection Viral	21
Atypical Pneumonia	173	Genital Infection	21

Staphylococcal Sepsis	171	Omphalitis	21
Papilloma Viral Infection	168	Intestinal Tuberculosis	21
Bacteraemia	167	Salpingitis	20
Clostridial Infection	165	Bacteriuria	20
Escherichia Urinary Tract Infection	165	Mumps	20
Infection Susceptibility Increased	160	Skin Candida	20
Colonic Abscess	158	Chorioretinitis	20
Cholecystitis Infective	155	Bronchitis Bacterial	20
Pseudomonas Infection	151	Tuberculosis Of Central Nervous System	20
Hordeolum	151	Tinea Versicolour	20
Covid-19 Pneumonia	147	Complicated Appendicitis	20
Infected Bite	141	Oesophageal Infection	20
Postoperative Abscess	141	Pharyngitis Bacterial	19
Nosocomial Infection	138	Escherichia Bacteraemia	19
Endocarditis	137	Diarrhoea Infectious	19
Labyrinthitis	136	Viral Pharyngitis	19
Abdominal Infection	136	Acute Pulmonary Histoplasmosis	19
Staphylococcal Skin Infection	131	Eczema Infected	19
Retinitis	130	Gastritis Bacterial	19
Perirectal Abscess	129	Lower Respiratory Tract Infection Viral	19
Appendicitis Perforated	128	Listeria Sepsis	19
Varicella	128	Ear Infection Staphylococcal	19
Gastrointestinal Bacterial Infection	127	Bone Tuberculosis	19
Groin Abscess	123	Endocarditis Bacterial	18
Pneumonia Fungal	120	Cerebral Toxoplasmosis	18
Mastitis	119	Infection In An Immunocompromised Host	18
Hepatitis B	118	Epiglottitis	18
Chikungunya Virus Infection	116	Gastrointestinal Candidiasis	18
Infected Cyst	115	Herpes Zoster Disseminated	18
Pilonidal Disease	115	Urinary Tract Infection Enterococcal	18
Tinea Pedis	114	Bacillus Infection	18
Liver Abscess	113	Cellulitis Orbital	18
Dengue Fever	113	Nasal Herpes	18
Fungal Foot Infection	112	Proteus Infection	17
Epstein-Barr Virus Infection	109	Pseudomonal Sepsis	17
Coccidioidomycosis	109	Febrile Infection	17
Nail Infection	108	Muscle Abscess	17
Otitis Media	100	Tracheobronchitis	17
Post Procedural Sepsis	98	Sexually Transmitted Disease	17
Pelvic Abscess	97	Scarlet Fever	17
Klebsiella Infection	96	Salmonella Sepsis	17
Gangrene	94	Hepatitis Viral	17
Intervertebral Discitis	94	Epstein-Barr Virus Infection Reactivation	17
Histoplasmosis Disseminated	94	Rocky Mountain Spotted Fever	17
Lymph Node Tuberculosis	94	Endocarditis Staphylococcal	17
Tinea Infection	93	Bartholin'S Abscess	17
Infected Fistula	93	Herpes Simplex Hepatitis	17
Injection Site Infection	92	Viral Rash	17
Mycobacterial Infection	92	Blastomycosis	16
Escherichia Sepsis	92	Chest Wall Abscess	16
Salmonellosis	92	Tubo-Ovarian Abscess	16
Infected Skin Ulcer	91	Biliary Sepsis	16
Lung Abscess	91	Otitis Media Acute	16

Enteritis Infectious	90	Oropharyngitis Fungal	16
Bacterial Sepsis	88	Measles	16
Empyema	87	Urinary Tract Infection Staphylococcal	16
Necrotising Fasciitis	87	Stitch Abscess	16
Meningitis Viral	87	Perichondritis	16
Impetigo	86	Carbuncle	16
Oesophageal Candidiasis	84	Cystitis Escherichia	16
Breast Abscess	84	Toxic Shock Syndrome	16
Large Intestine Infection	83	Q Fever	16
Paronychia	82	Mycobacterium Kansasii Infection	16
Ophthalmic Herpes Zoster	81	Systemic Infection	16
Mycobacterium Avium Complex Infection	80	Sebaceous Gland Infection	16
Bursitis Infective	80	Fungal Pharyngitis	16
Urinary Tract Infection Bacterial	79	Fournier'S Gangrene	15
Intestinal Sepsis	79	Croup Infectious	15
Spinal Cord Infection	77	Corynebacterium Infection	15
Skin Bacterial Infection	76	Bursitis Infective Staphylococcal	15
Genital Herpes	75	Periorbital Cellulitis	15
Pulpitis Dental	75	Incision Site Cellulitis	15
Pyoderma	74	Viral Myocarditis	15
Respiratory Tract Infection Viral	74	Amniotic Cavity Infection	15
H1n1 Influenza	74	Oophoritis	15
Bronchopulmonary Aspergillosis	73	Diabetic Foot Infection	15
Listeriosis	73	Herpes Zoster Oticus	15
Abscess Rupture	71	Post Viral Fatigue Syndrome	14
Aspergillus Infection	70	Tracheitis	14
Meningitis Aseptic	68	Adenoiditis	14
Pertussis	67	Pneumocystis Jirovecii Infection	14
Enterococcal Infection	66	Bacterial Pyelonephritis	14
Brain Abscess	66	Peritoneal Abscess	14
Varicella Zoster Virus Infection	66	Nail Bed Infection	14
Peritoneal Tuberculosis	66	Enterovirus Infection	14
Incision Site Abscess	65	Burn Infection	14
Prostate Infection	65	Appendiceal Abscess	14
Pathogen Resistance	64	Pneumonia Haemophilus	14
Hepatic Infection	64	Infective Tenosynovitis	14
Myelitis	63	Eye Infection Toxoplasmal	14
Abscess Oral	63	Paracoccidioides Infection	14
Herpes Ophthalmic	62	Flavivirus Infection	14
Lymph Gland Infection	62	Septic Embolus	13
Peritonsillar Abscess	61	Endometritis	13
Acarodermatitis	61	Superinfection Bacterial	13
Beta Haemolytic Streptococcal Infection	60	Sweat Gland Infection	13
Blister Infected	60	Viral Skin Infection	13
Gastroenteritis Norovirus	59	Implant Site Infection	13
Sialoadenitis	59	Syphilis	13
Stoma Site Abscess	59	Gastroenteritis Clostridial	13
Respiratory Syncytial Virus Infection	58	Serratia Infection	13
Encephalitis Viral	57	Nasal Abscess	13
Cellulitis Staphylococcal	57	Ovarian Abscess	13
Device Related Sepsis	57	Mycoplasma Infection	13
Gastrointestinal Viral Infection	56	Lymphadenitis Bacterial	13
Injection Site Cellulitis	55	Meningitis Pneumococcal	13

Bacterial Vaginosis	55	Infestation	13
Otitis Externa	55	Urinary Bladder Abscess	13
Abdominal Wall Abscess	55	Tuberculosis Liver	13
Tuberculosis Gastrointestinal	55	Tropical Infectious Disease	13
Vascular Device Infection	54	Mucocutaneous Leishmaniasis	13
Lupus Vulgaris	54	Peritonitis Bacterial	12
Helicobacter Gastritis	53	Staphylococcal Osteomyelitis	12
Pyelonephritis Acute	53	Actinomycosis	12
Legionella Infection	52	Urinary Tract Infection Fungal	12
Superinfection	51	Parvovirus Infection	12
Pneumonia Staphylococcal	51	Ear Infection Viral	12
Genital Abscess	51	Chronic Tonsillitis	12
Respiratory Tract Infection Bacterial	51	Mycobacterium Chelonae Infection	12
Soft Tissue Infection	50	Joint Tuberculosis	12
Meningitis Bacterial	49	Wound Infection Fungal	12
Bronchiolitis	49	Herpes Zoster Infection Neurological	12
Opportunistic Infection	49	Vulvitis	11
Stoma Site Infection	48	Breast Cellulitis	11
Pulmonary Sepsis	48	Pyomyositis	11
Dysentery	48	Acute Hepatitis B	11
Infectious Pleural Effusion	47	Infusion Site Infection	11
Abscess Neck	47	Osteomyelitis Chronic	11
Vulval Abscess	46	Urethritis	11
Staphylococcal Abscess	44	West Nile Viral Infection	11
Medical Device Site Infection	44	Encephalomyelitis	11
Cardiac Infection	43	Gastroenteritis Bacterial	11
Extradural Abscess	43	Oral Bacterial Infection	11
Progressive Multifocal Leukoencephalopathy	42	Relapsing Fever	11
Staphylococcal Bacteraemia	42	Streptococcal Urinary Tract Infection	11
Cutaneous Leishmaniasis	42	Immune Reconstitution Inflammatory Syndrome Associated Tuberculosis	11
Acne Pustular	42	Pneumonia Influenzal	11
Visceral Leishmaniasis	42	Mesenteric Abscess	11
Extrapulmonary Tuberculosis	42	External Ear Cellulitis	11
Gastroenteritis Salmonella	41	Eye Abscess	11
Streptococcal Sepsis	41	Leprosy	11
Root Canal Infection	41	Dengue Haemorrhagic Fever	11
Bacterial Vulvovaginitis	40	Colostomy Infection	11
Injection Site Pustule	40	Bacterial Abdominal Infection	11
Orchitis	40	Meningitis Cryptococcal	10
Infected Dermal Cyst	40	Clostridium Colitis	10
Pneumonia Pneumococcal	39	Bk Virus Infection	10
Periodontitis	39	Alpha Haemolytic Streptococcal Infection	10
Pneumonia Cryptococcal	39	Sinusitis Aspergillus	10
Acute Sinusitis	38	Fungaemia	10
Sinusitis Bacterial	38	Viral Sinusitis	10
Intestinal Fistula Infection	38	Lower Respiratory Tract Infection Bacterial	10
Cytomegalovirus Colitis	37	Pneumonia Necrotising	10
Tuberculous Pleurisy	37	Enterococcal Sepsis	10
Post Procedural Cellulitis	37	Candida Sepsis	10
Campylobacter Gastroenteritis	37	Mononucleosis Syndrome	10

Psoas Abscess	37	Hepatic Infection Fungal	10
Infection Parasitic	37	Dermo-Hypodermatitis	10
Renal Abscess	37	Mycobacterium Fortuitum Infection	10
Pneumonia Streptococcal	36	Graft Infection	10
Adenovirus Infection	36	Streptococcal Abscess	10
Wound Abscess	36	Upper Respiratory Tract Infection Bacterial	10
Vaginal Abscess	36	Ophthalmic Herpes Simplex	10
Dermatitis Infected	36	Cytomegalovirus Enteritis	10
Pelvic Inflammatory Disease	35	Gastritis Fungal	10
Abdominal Sepsis	35		

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.