Provision of Publicly Available FAERs Data for Actemra® (Tocilizumab)

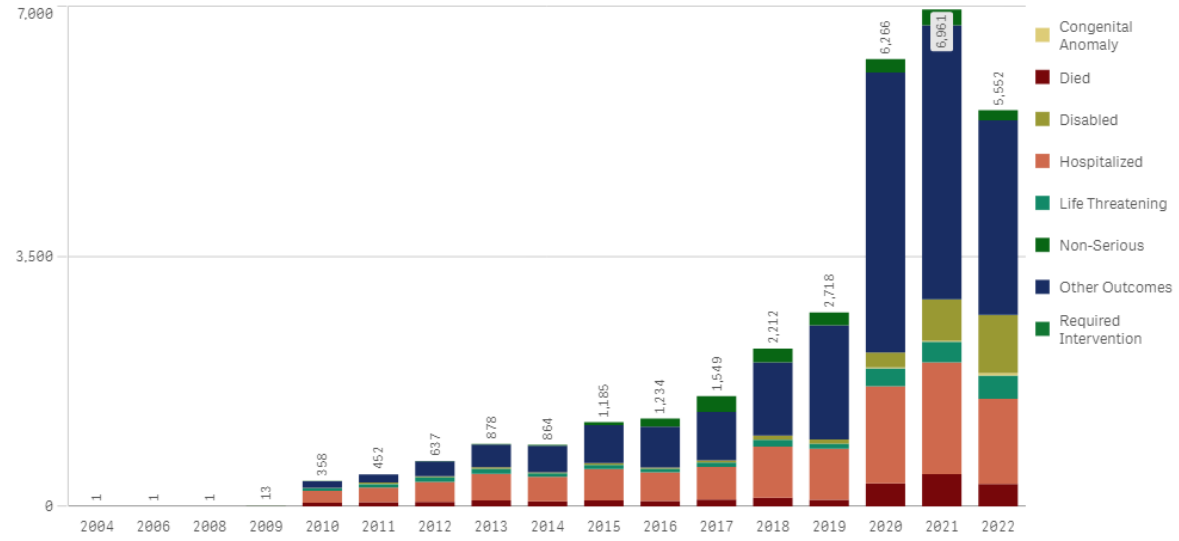
You are accessing this document as you are taking part in the Veradigm Adverse Event Deep-Dive Program, a GSK sponsored pilot program which aims to facilitate and evaluate a bi-directional communication process with a trusted third party using the Practice Fusion secure messaging system to enhance and 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 Actemra® (Tocilizumab) and all infections,*** with data as of 30 June 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 Actemra please contact the manufacturer Genentech on 1-888-835-2555.

Pre-filtered to Actemra® (Tocilizumab) and ALL INFECTIONS, with data as of 30 June 2022.

Outcome counts by Received Year



Case counts by Age Group and Sex

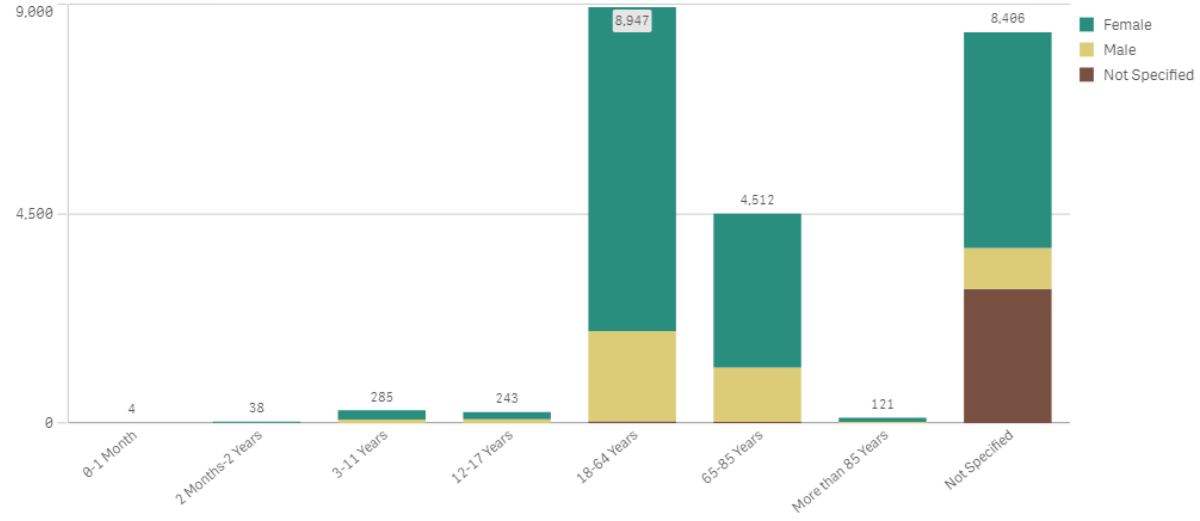


Table of Adverse Events of Infections (n≥10) (*Actemra® (Tocilizumab)*) with data as of 30 June 2022

Reaction Term	Count	Reaction Term	Count
Infection	4,297	Gangrene	28
Nasopharyngitis	3,803	Herpes Ophthalmic	28
Pneumonia	3,263	Breast Abscess	27
Sinusitis	2,813	Pneumonia Cytomegaloviral	27
Lower Respiratory Tract Infection	2,505	Ophthalmic Herpes Zoster	27
Helicobacter Infection	1,408	Spinal Cord Infection	27
Folliculitis	1,311	Escherichia Infection	26
Urinary Tract Infection	1,255	Infection Susceptibility Increased	26
Herpes Zoster	1,248	Mucormycosis	26
Diverticulitis	1,053	Fungaemia	25
Sepsis	1,010	Mycobacterial Infection	25
Influenza	995	Bursitis Infective	25
Bronchitis	954	Cytomegalovirus Infection Reactivation	25
Septic Shock	686	Viraemia	25
Cellulitis	651	Purulent Discharge	24
Upper Respiratory Tract Infection	648	Rash Pustular	24
Covid-19	648	Pyelonephritis Acute	24
Localised Infection	593	Respiratory Tract Infection Viral	24
Cystitis	401	Clostridium Difficile Colitis	23
Oral Herpes	378	Bk Virus Infection	23
Osteomyelitis	344	Urinary Tract Infection Bacterial	23
Ear Infection	334	Progressive Multifocal Leukoencephalopathy	22
Fungal Infection	322	Muscle Abscess	22
Pharyngitis	306	Pharyngeal Abscess	22
Pneumonia Bacterial	283	Appendicitis Perforated	21
Tooth Infection	271	Liver Abscess	21
Wound Infection	262	Hordeolum	21
Bacterial Infection	232	Pneumonia Klebsiella	21
Candida Infection	220	Polyomavirus-Associated Nephropathy	21
Respiratory Tract Infection	214	Large Intestine Infection	21
Staphylococcal Infection	212	Purulence	20
Arthritis Bacterial	208	Lyme Disease	19
Abscess	207	Meningitis Bacterial	19
Viral Infection	206	Infected Cyst	19
Kidney Infection	203	Abscess Intestinal	19
Gastroenteritis	193	Septic Arthritis Staphylococcal	19
Gastroenteritis Viral	192	Abscess Rupture	19
Laryngitis	184	Hepatitis C	18
Covid-19 Pneumonia	179	Pertussis	18
Tooth Abscess	172	Nosocomial Infection	18
Pneumonia Fungal	161	Oesophageal Candidiasis	18
Conjunctivitis	160	Periodontitis	18
Tuberculosis	160	Varicella Zoster Virus Infection	18
Onychomycosis	159	Infected Dermal Cyst	18
Pneumonia Viral	158	Disseminated Mucormycosis	18
Peritonitis	153	Genital Herpes	17
Bronchopulmonary Aspergillosis	151	Pathogen Resistance	17
Skin Infection	150	Stenotrophomonas Infection	17
Pyelonephritis	149	Pneumonia Pneumococcal	17

Viral Upper Respiratory Tract Infection	145	Extradural Abscess	17
Arthritis Infective	142	Human Herpesvirus 6 Infection	17
Bacteraemia	141	Oropharyngeal Candidiasis	16
Pneumocystis Jirovecii Pneumonia	140	Tinea Pedis	16
Eye Infection	116	Cytomegalovirus Enterocolitis	16
Clostridium Difficile Infection	111	Hepatitis B	16
Post Procedural Infection	110	Superinfection Bacterial	16
Abscess Limb	107	Opportunistic Infection	16
Cytomegalovirus Infection	103	Atypical Mycobacterial Infection	16
Erysipelas	101	Respiratory Tract Infection Bacterial	16
Meningitis	97	Endocarditis Bacterial	15
Furuncle	95	Helicobacter Gastritis	15
Pharyngitis Streptococcal	90	Cholecystitis Infective	15
Device Related Infection	88	Acarodermatitis	15
Herpes Virus Infection	86	Root Canal Infection	15
Tonsillitis	85	Renal Abscess	15
Urosepsis	83	Hepatitis E	15
Encephalitis	82	Pulpitis Dental	15
Postoperative Wound Infection	82	Pseudomonal Bacteraemia	15
Gastric Infection	80	Whipple'S Disease	15
Endocarditis	74	Psoas Abscess	15
Pneumonia Aspiration	73	Enterobacter Infection	15
Anal Abscess	73	Infective Spondylitis	15
Systemic Candida	72	Vulvovaginal Mycotic Infection	14
Retinitis	72	Acute Sinusitis	14
Rhinitis	70	Infectious Mononucleosis	14
Vaginal Infection	70	Pelvic Abscess	14
Infected Skin Ulcer	69	Disseminated Tuberculosis	14
Aspergillus Infection	68	Pustule	14
Necrotising Fasciitis	67	Perineal Infection	14
Oral Candidiasis	67	Epstein-Barr Virus Infection Reactivation	14
Gastrointestinal Infection	63	Central Nervous System Infection	13
Pseudomonas Infection	61	Endophthalmitis	13
Gingivitis	60	Brain Abscess	13
Otitis Media	57	Vascular Device Infection	13
Enteritis Infectious	56	Nocardiosis	13
Infected Bite	56	Tracheobronchitis	13
Subcutaneous Abscess	55	Enterococcal Bacteraemia	13
Appendicitis	54	Croup Infectious	13
Infectious Pleural Effusion	53	Scrotal Infection	13
Enterococcal Infection	52	Cellulitis Staphylococcal	12
Staphylococcal Sepsis	51	Meningitis Aseptic	12
Abdominal Abscess	51	Beta Haemolytic Streptococcal Infection	12
Escherichia Urinary Tract Infection	50	Diarrhoea Infectious	12
Staphylococcal Bacteraemia	50	Tracheitis	12
Klebsiella Infection	48	Pelvic Inflammatory Disease	12
Bacterial Sepsis	47	Superinfection	12
Intestinal Sepsis	46	Colonic Abscess	12
Chronic Sinusitis	45	Pneumonia Escherichia	12
Paronychia	44	Pyelitis	12
Coronavirus Infection	44	Cellulitis Gangrenous	12
Pulmonary Tuberculosis	42	Escherichia Bacteraemia	11
Empyema	42	Device Related Sepsis	11

Oral Infection	40	Cytomegalovirus Colitis	11
Nail Infection	40	Papilloma Viral Infection	11
Lung Abscess	39	Otitis Media Acute	11
Cytomegalovirus Viraemia	39	Pneumonia Cryptococcal	11
Systemic Infection	39	Lip Infection	11
Fungal Skin Infection	38	Toxic Shock Syndrome	11
Epstein-Barr Viraemia	38	Enterococcal Sepsis	10
Labyrinthitis	37	Abdominal Infection	10
Pneumonia Pseudomonal	37	Tubo-Ovarian Abscess	10
Encephalitis Viral	37	Bone Abscess	10
Intervertebral Discitis	35	Epididymitis	10
Hepatitis B Reactivation	35	Otitis Externa	10
Herpes Simplex	33	Myelitis	10
Epstein-Barr Virus Infection	32	Haematoma Infection	10
Adenovirus Infection	32	Histoplasmosis	10
Streptococcal Infection	32	Legionella Infection	10
Bronchitis Viral	31	Skin Bacterial Infection	10
Lupus Vulgaris	31	Joint Abscess	10
Soft Tissue Infection	30	Herpes Simplex Reactivation	10
Pneumonia Staphylococcal	29	Infective Exacerbation Of Bronchiectasis	10
Varicella	29	Genital Herpes Simplex	10
Escherichia Sepsis	29	Rubella	10
Latent Tuberculosis	29	Sebaceous Gland Infection	10

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.