Provision of Publicly Available FAERs Data for Cimza® (Certolizumab pegol)

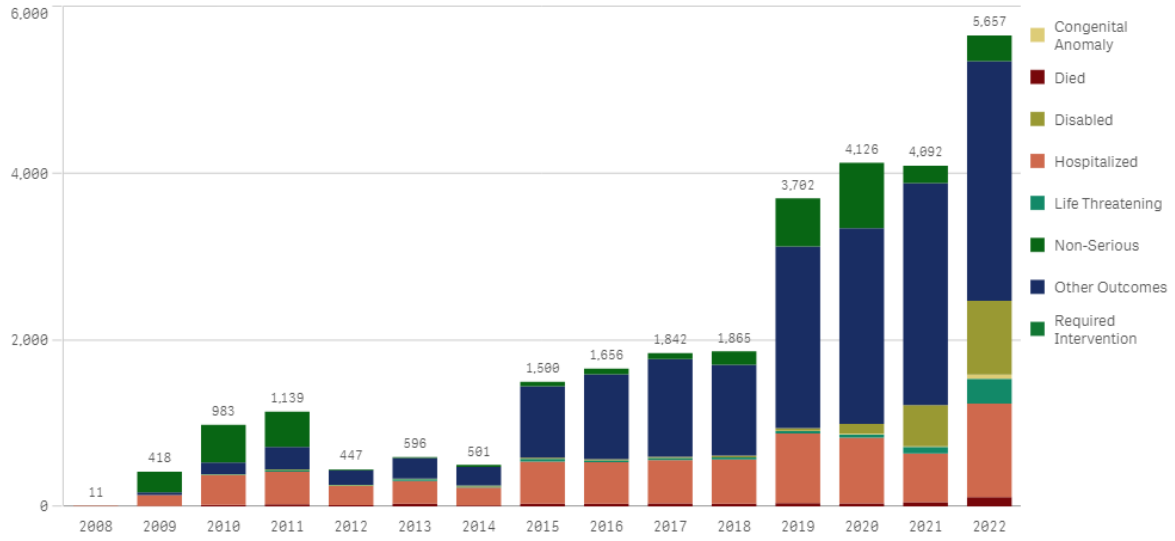
You are accessing this document as you are taking part in the Veradigm Adverse Event Deep-Dive Program, a GSK sponsored pilot program which aims to facilitate and evaluate a bi-directional communication process with a trusted third party using the Practice Fusion secure messaging system to enhance and 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 Cimza® (Certolizumab pegol) 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 Cimza please contact the manufacturer UCB on 1-888-599- 2273.

Pre-filtered to Cimza® (Certolizumab pegol) and ALL INFECTIONS, with data as of 30 September 2022.

Outcome counts by Received Year



Case counts by Age Group and Sex

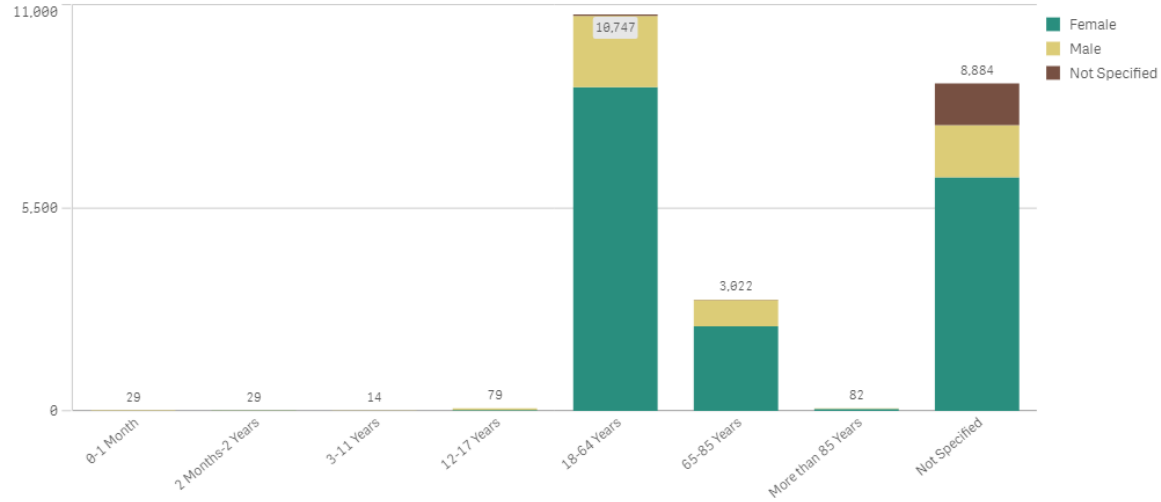


Table of Adverse Events of Infections (n≥10) (*Cimza® (Certolizumab pegol)*) with data as of 30 September 2022

Reaction Term	Count	Reaction Term	Count
Infection	3,616	Pustule	32
Sinusitis	2,961	Covid-19 Pneumonia	29
Nasopharyngitis	2,960	Oesophageal Candidiasis	28
Lower Respiratory Tract Infection	2,856	Varicella	28
Pneumonia	2,696	Oral Fungal Infection	28
Urinary Tract Infection	1,634	Atypical Pneumonia	27
Helicobacter Infection	1,464	Clostridium Difficile Colitis	26
Folliculitis	1,411	Otitis Media	26
Covid-19	1,116	Herpes Simplex	25
Bronchitis	963	Infectious Mononucleosis	24
Herpes Zoster	945	Lymph Node Tuberculosis	23
Influenza	892	Labyrinthitis	22
Upper Respiratory Tract Infection	598	Groin Abscess	22
Cellulitis	567	Pneumonia Viral	22
Sepsis	428	Bronchiolitis	21
Ear Infection	392	Escherichia Urinary Tract Infection	21
Diverticulitis	334	Cytomegalovirus Infection	20
Fungal Infection	329	Bacteraemia	20
Tuberculosis	322	Bacterial Vaginosis	20
Cystitis	309	Pneumonia Aspiration	19
Localised Infection	307	Pertussis	19
Staphylococcal Infection	306	Impetigo	19
Kidney Infection	297	Infectious Pleural Effusion	19
Abscess	296	Hordeolum	19
Viral Infection	270	Injection Site Infection	18
Respiratory Tract Infection	252	Meningitis Viral	18
Tooth Infection	218	Viral Upper Respiratory Tract Infection	18
Oral Herpes	191	Liver Abscess	18
Pharyngitis	187	Tuberculous Pleurisy	18
Clostridium Difficile Infection	185	Chronic Sinusitis	18
Pharyngitis Streptococcal	181	Infected Bite	18
Gastroenteritis Viral	178	Abscess Oral	18
Osteomyelitis	174	Empyema	17
Wound Infection	173	Respiratory Tract Infection Viral	17
Onychomycosis	159	Intervertebral Discitis	17
Candida Infection	155	H1n1 Influenza	17
Laryngitis	146	Peritoneal Tuberculosis	17
Oral Candidiasis	137	Genital Herpes	16
Tooth Abscess	136	Vulvovaginal Candidiasis	16
Pyelonephritis	125	Meningitis Aseptic	16
Tonsillitis	125	Tinea Infection	16
Furuncle	120	Ophthalmic Herpes Zoster	16
Anal Abscess	118	Breast Abscess	16
Skin Infection	113	Pneumonia Pneumococcal	15
Post Procedural Infection	112	Hepatitis B	15
Abdominal Abscess	109	Pelvic Abscess	15
Gastroenteritis	106	Paronychia	15
Eye Infection	106	Purulent Discharge	15
Bacterial Infection	102	Nail Infection	15
Conjunctivitis	101	Parotitis	15
Septic Shock	97	Infected Cyst	15

Arthritis Bacterial	94	Hepatitis E	14
Gastrointestinal Infection	92	Mycobacterial Infection	14
Pulmonary Tuberculosis	92	Croup Infectious	14
Latent Tuberculosis	87	Appendicitis Perforated	14
Arthritis Infective	85	Infection Susceptibility Increased	14
Postoperative Wound Infection	83	Psoas Abscess	14
Pneumocystis Jirovecii Pneumonia	78	Abdominal Wall Abscess	14
Erysipelas	77	Borrelia Infection	14
Herpes Virus Infection	76	Aspergillus Infection	13
Retinitis	76	Meningitis Bacterial	13
Subcutaneous Abscess	74	Gastroenteritis Norovirus	13
Vulvovaginal Mycotic Infection	69	Endocarditis	13
Rectal Abscess	68	Peritonsillar Abscess	13
Streptococcal Infection	65	Abdominal Infection	13
Urosepsis	65	Cholecystitis Infective	13
Meningitis	64	Helicobacter Gastritis	13
Oral Infection	62	Hepatitis C	12
Pneumonia Bacterial	57	Respiratory Syncytial Virus Infection	12
Appendicitis	54	Lung Abscess	12
Lupus Vulgaris	52	Papilloma Viral Infection	12
Device Related Infection	51	Uterine Infection	12
Suspected Covid-19	51	Tinea Pedis	12
Abscess Limb	50	Herpes Ophthalmic	12
Abscess Intestinal	48	Urinary Tract Infection Bacterial	12
Rhinitis	47	Legionella Infection	12
Gingivitis	47	Infected Fistula	12
Clostridial Infection	47	Gastrointestinal Viral Infection	12
Enteritis Infectious	47	Systemic Infection	12
Escherichia Infection	46	Enterococcal Infection	11
Perirectal Abscess	46	Escherichia Sepsis	11
Vaginal Infection	44	Staphylococcal Abscess	11
Disseminated Tuberculosis	43	Pneumocystis Jirovecii Infection	11
Encephalitis	42	Staphylococcal Skin Infection	11
Coronavirus Infection	40	Salmonellosis	11
Fungal Skin Infection	39	Histoplasmosis	11
Dengue Fever	39	Atypical Mycobacterial Infection	11
Mastitis	37	Perineal Abscess	11
Rash Pustular	37	Bursitis Infective	11
Pyelonephritis Acute	36	Infected Skin Ulcer	10
Staphylococcal Sepsis	34	Pyoderma	10
Peritonitis	34	Escherichia Bacteraemia	10
Encephalitis Viral	33	Colonic Abscess	10
Gastric Infection	33	Otitis Externa	10
Lyme Disease	32	Mononucleosis Syndrome	10
Pneumonia Legionella	32		

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.