Provision of Publicly Available FAERs Data for Simponi® (Golimumab)

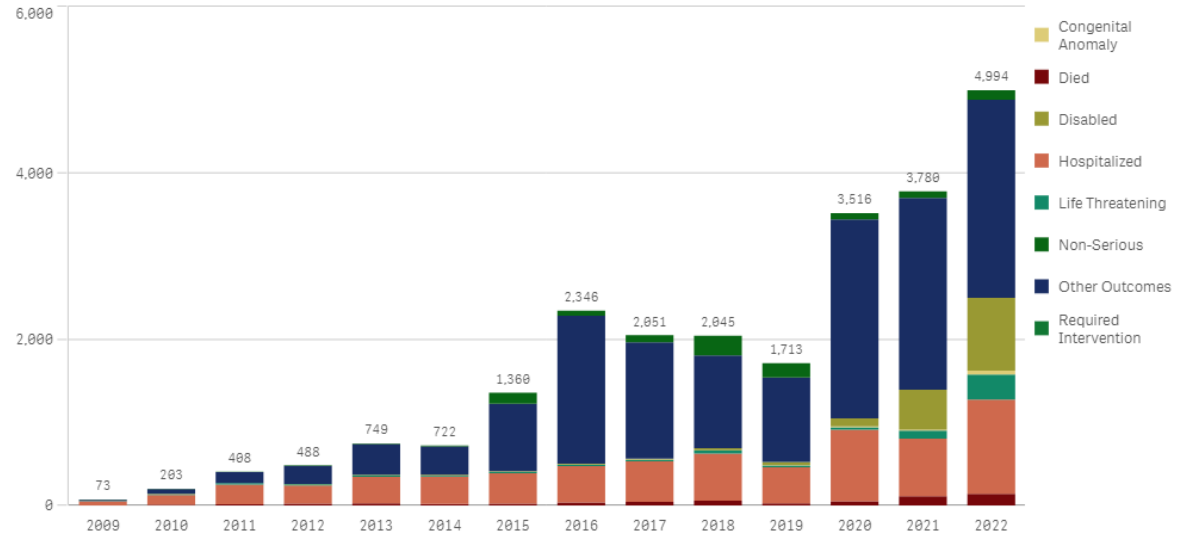
You are accessing this document as you are taking part in the Veradigm Adverse Event Deep-Dive Program, a GSK sponsored pilot program which aims to facilitate and evaluate a bi-directional communication process with a trusted third party using the Practice Fusion secure messaging system to enhance and 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 Simponi® (Golimumab) 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 Simponi please contact the manufacturer Janssen on 1-800-526-7736.

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

Outcome counts by Received Year



Case counts by Age Group and Sex

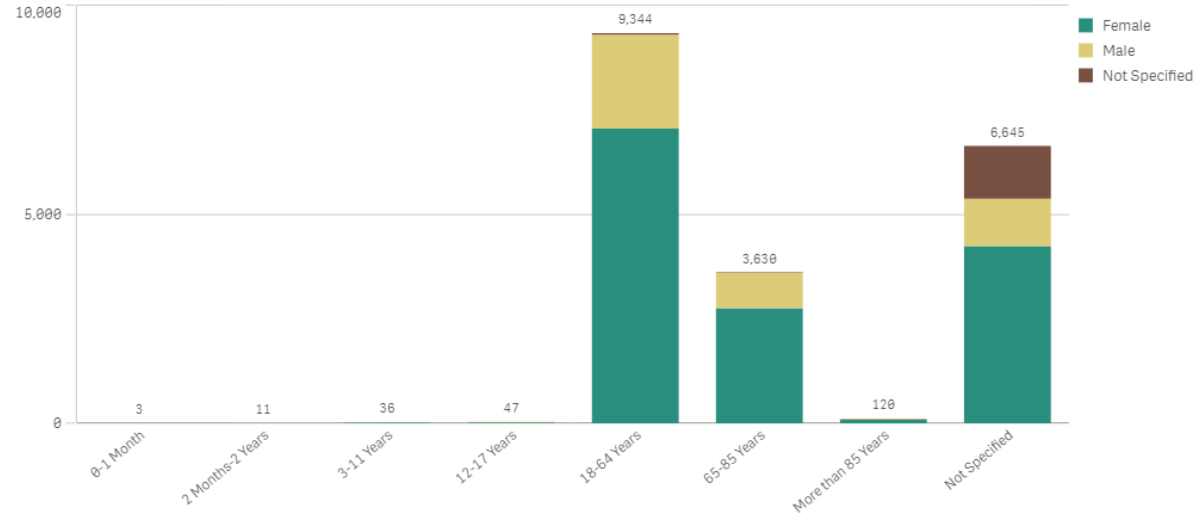


Table of Adverse Events of Infections (n≥10) (*Simponi® (Golimumab)*) with data as of 30 September 2022

Reaction Term	Count	Reaction Term	Count
Lower Respiratory Tract Infection	3,425	Nosocomial Infection	25
Infection	3,020	Helicobacter Gastritis	25
Pneumonia	2,755	Lymph Node Tuberculosis	23
Sinusitis	2,392	Flavivirus Infection	23
Nasopharyngitis	2,285	Meningitis Viral	22
Helicobacter Infection	1,474	Infectious Pleural Effusion	22
Folliculitis	1,383	Urinary Tract Infection Bacterial	22
Urinary Tract Infection	1,194	Pertussis	21
Influenza	849	Ophthalmic Herpes Zoster	21
Covid-19	680	Atypical Mycobacterial Infection	21
Herpes Zoster	587	Bacteraemia	20
Cellulitis	578	Coronavirus Infection	20
Bronchitis	485	Uterine Infection	20
Sepsis	371	Intervertebral Discitis	20
Diverticulitis	328	Paronychia	19
Tuberculosis	308	Respiratory Tract Infection Viral	19
Respiratory Tract Infection	287	Mycobacterium Marinum Infection	19
Ear Infection	276	Pneumonia Viral	19
Upper Respiratory Tract Infection	266	Suspected Covid-19	19
Kidney Infection	266	Staphylococcal Sepsis	18
Osteomyelitis	233	Encephalitis	18
Viral Infection	230	Mycobacterial Infection	18
Tooth Abscess	230	Herpes Simplex	18
Wound Infection	224	Endocarditis	18
Pharyngitis	221	Liver Abscess	18
Localised Infection	197	Peritonsillar Abscess	18
Tooth Infection	179	Chronic Sinusitis	18
Cystitis	160	Peritoneal Tuberculosis	18
Staphylococcal Infection	157	Purulence	17
Onychomycosis	155	Cytomegalovirus Colitis	17
Clostridium Difficile Infection	145	Soft Tissue Infection	17
Laryngitis	145	Hordeolum	17
Post Procedural Infection	127	Otitis Media	17
Abscess	126	Atypical Pneumonia	17
Tonsillitis	123	Salmonellosis	17
Pulmonary Tuberculosis	121	Gastritis Bacterial	17
Oral Herpes	119	Bronchiolitis	16
Pyelonephritis	119	Borrelia Infection	16
Gastrointestinal Infection	112	Fungal Skin Infection	15
Dengue Fever	112	Epstein-Barr Virus Infection	15
Fungal Infection	99	Whipple'S Disease	15
Septic Shock	98	Cholecystitis Infective	15
Gastroenteritis	98	Histoplasmosis	15
Pneumocystis Jirovecii Pneumonia	97	Groin Abscess	15
Herpes Virus Infection	92	Pneumonia Aspiration	14
Pneumonia Bacterial	91	Clostridium Difficile Colitis	14
Skin Infection	91	Mastitis	14
Candida Infection	90	Papilloma Viral Infection	14
Postoperative Wound Infection	90	Lower Respiratory Tract Infection Bacterial	14
Erysipelas	90	Pneumonia Fungal	14
Conjunctivitis	89	Bursitis Infective	14
Gastroenteritis Viral	89	Abscess Intestinal	13

Arthritis Bacterial	88	Gastroenteritis Salmonella	13
Appendicitis	87	Pulpitis Dental	13
Bacterial Infection	84	H1n1 Influenza	13
Arthritis Infective	82	Enteritis Infectious	13
Retinitis	78	Prostate Infection	13
Anal Abscess	74	Syphilis	13
Furuncle	72	Genital Herpes	12
Abscess Limb	69	Vulvovaginal Candidiasis	12
Oral Candidiasis	67	Oesophageal Candidiasis	12
Covid-19 Pneumonia	67	Appendicitis Perforated	12
Rhinitis	64	Sialoadenitis	12
Latent Tuberculosis	64	Gangrene	11
Viral Upper Respiratory Tract Infection	63	Impetigo	11
Eye Infection	62	Injection Site Infection	11
Device Related Infection	61	Necrotising Fasciitis	11
Subcutaneous Abscess	59	Rectal Abscess	11
Vaginal Infection	56	Vulvovaginal Mycotic Infection	11
Lupus Vulgaris	52	Lung Abscess	11
Cytomegalovirus Infection	51	Purulent Discharge	11
Urosepsis	51	Clostridial Infection	11
Hepatitis B Reactivation	43	Nail Infection	11
Gastric Infection	40	Acute Sinusitis	11
Peritonitis	39	Opportunistic Infection	11
Gingivitis	38	Epididymitis	11
Pharyngitis Streptococcal	38	Infected Bite	11
Pustule	34	Dysentery	11
Disseminated Tuberculosis	33	Renal Abscess	11
Varicella	32	Administration Site Infection	11
Pyelonephritis Acute	32	Zika Virus Infection	11
Infected Cyst	32	Streptococcal Infection	10
Hepatitis C	30	Escherichia Sepsis	10
Infected Skin Ulcer	29	Gastroenteritis Norovirus	10
Abdominal Abscess	29	Infectious Mononucleosis	10
Labyrinthitis	29	Meningitis Aseptic	10
Oral Infection	29	Cerebral Toxoplasmosis	10
Escherichia Urinary Tract Infection	28	Pharyngotonsillitis	10
Meningitis	27	Oral Fungal Infection	10
Tuberculous Pleurisy	27	Enterobacter Infection	10
Chikungunya Virus Infection	27	Stenotrophomonas Infection	10
Hepatitis B	26	Breast Abscess	10
Lyme Disease	26	Pulmonary Sepsis	10
Rash Pustular	26	Abscess Oral	10
Escherichia Infection	26	Pneumonia Cryptococcal	10
Pneumonia Legionella	25	Fungal Foot 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.