

## **Provision of Publicly Available FAERs Data for Tremfya® (Guselkumab)**

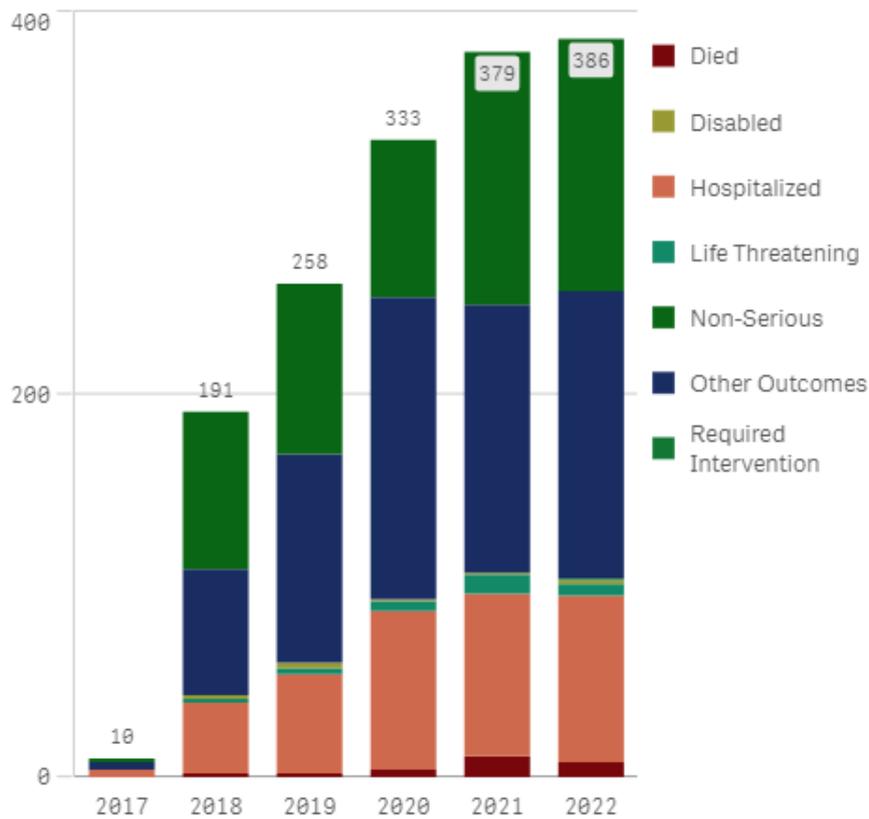
You are accessing this document as you are taking part in the Veradigm Adverse Event Deep-Dive Program, a GSK sponsored pilot program which aims to facilitate and evaluate a bi-directional communication process with a trusted third party using the Practice Fusion secure messaging system to enhance and 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 Tremfya® (Guselkumab) and all infections*, with data as of 30 June 2022.

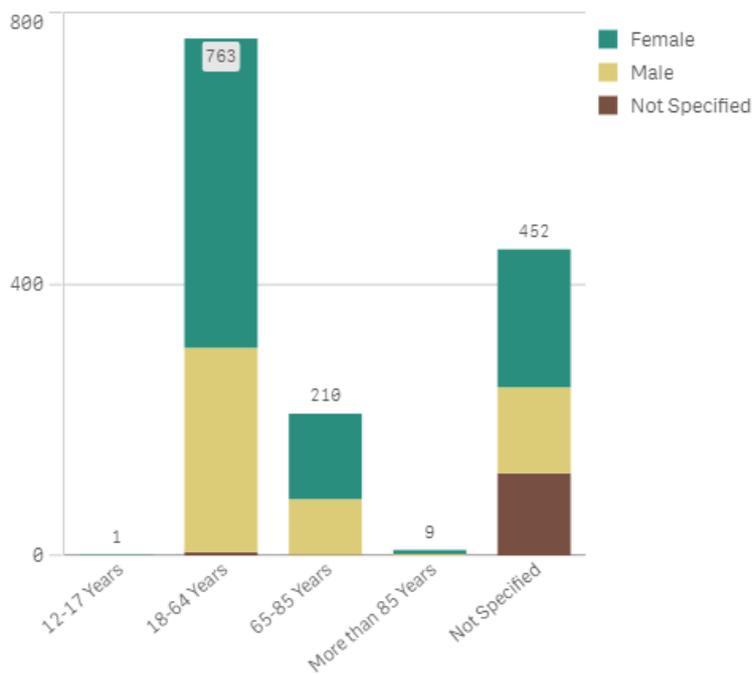
The information provided below is for **information purposes only**, when using this data, you should be aware that there are a number of limitations, these are described in detail in this document and available on the FAERs public dashboard website. If you have any questions related to Tremfya please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

**Pre-filtered to Tremfya® (Guselkumab) 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 (*Tremfya*® (*Guselkumab*)) with data as of 30 June 2022**

Reaction Term	Count	Reaction Term	Count
Pneumonia	193	Appendiceal Abscess	2
Covid-19	183	Genital Herpes Simplex	2
Nasopharyngitis	89	Cross Infection	2
Lower Respiratory Tract Infection	81	Gastroenteritis Salmonella	1
Infection	80	Peritonitis	1
Cellulitis	68	Escherichia Infection	1
Influenza	52	Bacterial Vaginosis	1
Sinusitis	45	Rhinitis	1
Upper Respiratory Tract Infection	44	Groin Infection	1
Urinary Tract Infection	43	Encephalitis	1
Respiratory Tract Infection	41	Respiratory Syncytial Virus Infection	1
Bronchitis	40	Bacterial Sepsis	1
Sepsis	33	Gingivitis	1
Herpes Zoster	30	Escherichia Bacteraemia	1
Fungal Infection	27	Enteritis Infectious	1
Localised Infection	22	Vulvovaginal Mycotic Infection	1
Kidney Infection	20	Injection Site Cellulitis	1
Oral Herpes	20	Pneumonia Aspiration	1
Diverticulitis	19	Genital Herpes	1
Ear Infection	19	Cystitis Bacterial	1
Staphylococcal Infection	16	Atypical Pneumonia	1
Tuberculosis	16	Pneumonia Staphylococcal	1
Cystitis	15	Meningoencephalitis Herpetic	1
Septic Shock	15	Cholecystitis Infective	1
Viral Infection	15	Gastrointestinal Candidiasis	1
Covid-19 Pneumonia	15	Oral Fungal Infection	1
Abscess	14	Impetigo	1
Skin Infection	11	Pelvic Abscess	1
Bacterial Infection	10	Tubo-Ovarian Abscess	1
Gastroenteritis	10	Syphilis	1
Hepatitis C	9	Varicella	1
Subcutaneous Abscess	9	Actinomycosis	1
Herpes Virus Infection	9	Device Related Sepsis	1
Pneumonia Bacterial	9	Morganella Infection	1
Herpes Simplex	9	Pneumococcal Sepsis	1
Tooth Infection	9	Rectal Abscess	1
Coronavirus Infection	9	Tracheitis	1
Latent Tuberculosis	8	Pyelonephritis Acute	1
Pustule	7	Tinea Cruris	1
Gastroenteritis Viral	6	Bone Abscess	1
Appendicitis	6	Oesophageal Candidiasis	1
Clostridium Difficile Infection	6	Infected Skin Ulcer	1
Pharyngitis Streptococcal	6	Helicobacter Infection	1
Pharyngitis	5	Oophoritis	1
Candida Infection	5	Paronychia	1
Tonsillitis	5	Lung Abscess	1
Erysipelas	5	Respiratory Tract Infection Viral	1
Suspected Covid-19	5	Hepatitis E	1
Eye Infection	4	Acinetobacter Infection	1
Laryngitis	4	Superinfection	1
Wound Infection	4	Virologic Failure	1
Pyelonephritis	4	Bronchiolitis	1
Tooth Abscess	4	Intervertebral Discitis	1

Furuncle	4	Gastric Infection	1
Tinea Infection	4	Epididymitis	1
Hordeolum	4	Viral Upper Respiratory Tract Infection	1
Postoperative Wound Infection	4	Postoperative Abscess	1
Streptococcal Infection	4	Superinfection Bacterial	1
Fungal Foot Infection	4	Salmonellosis	1
Escherichia Pyelonephritis	4	Otitis Media Acute	1
Bacteraemia	3	Opportunistic Infection	1
Post Procedural Infection	3	Eczema Impetiginous	1
Staphylococcal Sepsis	3	Pharyngeal Abscess	1
Urosepsis	3	Meningitis Herpes	1
Osteomyelitis	3	Hepatitis B Reactivation	1
Hiv Infection	3	Urinary Tract Infection Bacterial	1
Gastrointestinal Infection	3	Abscess Oral	1
Epstein-Barr Virus Infection	3	Dermo-Hypodermatitis	1
Pulmonary Tuberculosis	3	Nail Infection	1
Oral Infection	3	Perichondritis	1
Arthritis Infective	3	Meningitis Viral	1
Hepatitis B	3	Periorbital Cellulitis	1
Mycobacterium Avium Complex Infection	3	Pneumonia Pneumococcal	1
Folliculitis	3	Infected Bite	1
Ophthalmic Herpes Zoster	3	Skin Candida	1
Prostate Infection	3	Febrile Infection	1
Conjunctivitis	2	Legionella Infection	1
Appendicitis Perforated	2	Enterocolitis Viral	1
Abscess Limb	2	Infectious Pleural Effusion	1
Mastitis	2	Atypical Mycobacterial Infection	1
Pneumocystis Jirovecii Pneumonia	2	Pneumonia Necrotising	1
Meningitis	2	Ecthyma	1
Hepatitis A	2	Eye Infection Fungal	1
Staphylococcal Abscess	2	Bacterial Pyelonephritis	1
Onychomycosis	2	Enterococcal Bacteraemia	1
Vaginal Infection	2	Abscess Neck	1
Anal Abscess	2	Sinusitis Aspergillus	1
Vulvovaginal Candidiasis	2	Hand-Foot-And-Mouth Disease	1
Neutropenic Sepsis	2	Medical Device Site Infection	1
Rash Pustular	2	Tinea Versicolour	1
Infectious Mononucleosis	2	Spinal Cord Infection	1
Acarodermatitis	2	Anal Infection	1
Viral Pericarditis	2	Aspergilloma	1
Fungal Skin Infection	2	Respiratory Tract Infection Bacterial	1
Pneumonia Streptococcal	2	Pneumonia Influenzal	1
Escherichia Urinary Tract Infection	2	Dermatitis Infected	1
Pneumonia Viral	2	Dacryocystitis	1
Body Tinea	2	Perinephric Abscess	1
Papilloma Viral Infection	2	Tuberculosis Of Intrathoracic Lymph Nodes	1
Herpes Zoster Disseminated	2	Testicular Abscess	1
Infected Cyst	2	Acute Hepatitis C	1
Sialoadenitis	2	Mucocutaneous Candidiasis	1
Lower Respiratory Tract Infection Bacterial	2	Systemic Infection	1
Anorectal Infection	2	Abscess Of External Auditory Meatus	1
Coccidioidomycosis	2		

## **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%<sup>4</sup>. 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.