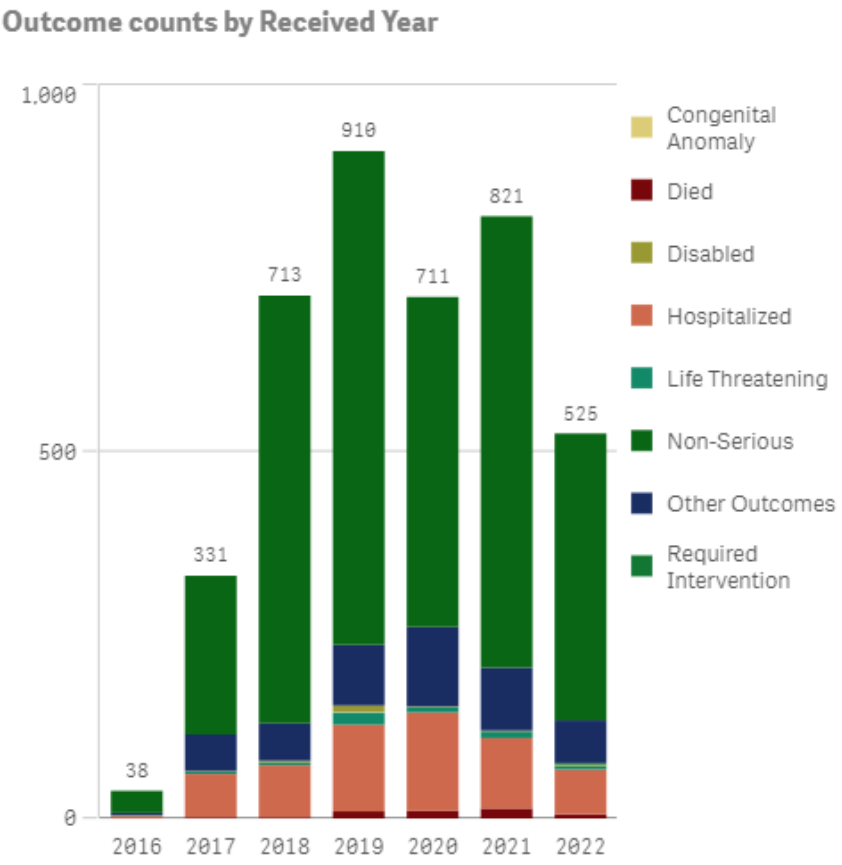
Provision of Publicly Available FAERs Data for Taltz® (Ixekizumab)

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 Taltz® (Ixekizumab) 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 Taltz please contact the manufacturer Eli Lilly on 1-800-545-5979.

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



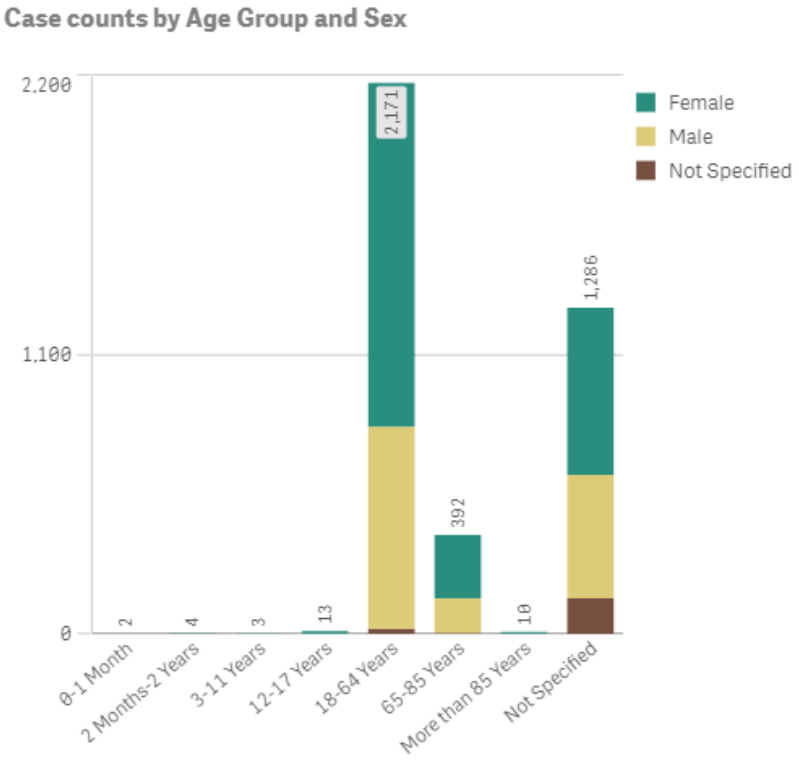


Table of Adverse Events of Infections (*Taltz® (Ixekizumab)*) with data as of 30 June 2022

Reaction Term	Count	Reaction Term	Count
Covid-19	374	Pyelonephritis Acute	2
Nasopharyngitis	310	Cytomegalovirus Colitis	2
Sinusitis	281	Hepatitis B	2
Infection	280	Superinfection	2
Urinary Tract Infection	210	Herpes Zoster Disseminated	2
Pneumonia	186	Lymphangitis	2
Cellulitis	183	Mycobacterial Infection	2
Influenza	169	Ophthalmic Herpes Zoster	2
Ear Infection	140	Abscess Intestinal	2
Upper Respiratory Tract Infection	135	Soft Tissue Infection	2
Fungal Infection	121	Urinary Tract Infection Bacterial	2
Bronchitis	115	Nail Infection	2
Herpes Zoster	99	Infection Parasitic	2
Candida Infection	94	Histoplasmosis	2
Oral Candidiasis	93	Infectious Pleural Effusion	2
Staphylococcal Infection	79	Diabetic Foot Infection	2
Sepsis	69	Bacterial Pyelonephritis	2
Pharyngitis Streptococcal	67	Skin Bacterial Infection	2
Tooth Infection	66	Abscess Neck	2
Localised Infection	60	Abscess Bacterial	2
Diverticulitis	46	Coccidioidomycosis	2
Cystitis	45	Tinea Capitis	2
Viral Infection	40	Infective Glossitis	2
Injection Site Cellulitis	37	Nasal Vestibulitis	2
Gastroenteritis Viral	35	Dientamoeba Infection	2
Respiratory Tract Infection	35	Gastroenteritis Salmonella	1
Kidney Infection	31	Device Related Infection	1
Conjunctivitis	29	Appendicitis Perforated	1
Tuberculosis	29	Pneumocystis Jirovecii Pneumonia	1
Streptococcal Infection	29	Progressive Multifocal Leukoencephalopathy	1
Eye Infection	27	Injection Site Abscess	1
Bacterial Infection	26	Respiratory Syncytial Virus Infection	1
Pharyngitis	26	Otitis Media	1
Skin Infection	26	Pneumonia Fungal	1
Furuncle	24	Purulent Discharge	1
Abscess	21	Bacterial Sepsis	1
Erysipelas	20	Gastroenteritis Norovirus	1
Lower Respiratory Tract Infection	18	Endocarditis Bacterial	1
Tinea Infection	18	Septic Embolus	1
Pustule	17	Helicobacter Gastritis	1
Osteomyelitis	16	Upper Respiratory Fungal Infection	1
Oral Herpes	16	Enteritis Infectious	1
Tooth Abscess	16	Onychomycosis	1
Coronavirus Infection	16	Epstein-Barr Virus Infection	1
Covid-19 Pneumonia	16	Central Nervous System Infection	1
Vulvovaginal Mycotic Infection	14	Oropharyngeal Candidiasis	1
Oral Fungal Infection	14	Jc Virus Infection	1
Folliculitis	14	Herpes Simplex	1
Rhinitis	13	Hepatitis Viral	1

Septic Shock	13	Pertussis	1
Laryngitis	13	Neonatal Infection	1
Tinea Pedis	13	Nosocomial Infection	1
Impetigo	13	Varicella	1
Tonsillitis	13	Viral Pericarditis	1
Post Procedural Infection	11	Vascular Device Infection	1
Gastrointestinal Infection	11	Retroperitoneal Abscess	1
Fungal Skin Infection	11	Pneumonia Klebsiella	1
Oesophageal Candidiasis	11	Escherichia Urinary Tract Infection	1
Gastroenteritis	10	Bacillus Infection	1
Hordeolum	10	Infected Skin Ulcer	1
Fungal Foot Infection	10	Pelvic Inflammatory Disease	1
Subcutaneous Abscess	9	Implant Site Infection	1
Injection Site Infection	8	Respiratory Tract Infection Viral	1
Appendicitis	8	Klebsiella Infection	1
Herpes Virus Infection	8	Urethritis	1
Helicobacter Infection	8	Papilloma Viral Infection	1
Clostridium Difficile Infection	7	Fungal Sepsis	1
Gingivitis	7	Intervertebral Discitis	1
Anal Abscess	7	Infected Cyst	1
Tinea Cruris	7	Lice Infestation	1
Clostridium Difficile Colitis	6	Listeriosis	1
Urosepsis	6	Eye Infection Staphylococcal	1
Necrotising Fasciitis	6	Eczema Herpeticum	1
Abdominal Abscess	6	Sinusitis Fungal	1
Wound Infection	6	Meningitis Cryptococcal	1
Pyelonephritis	6	Pulpitis Dental	1
Oral Infection	6	Staphylococcal Osteomyelitis	1
Groin Abscess	6	Otitis Media Acute	1
Postoperative Wound Infection	6	Candida Sepsis	1
Staphylococcal Skin Infection	6	Bursitis Infective	1
Sialoadenitis	6	Pharyngeal Abscess	1
Asymptomatic Covid-19	6	Nocardiosis	1
Escherichia Infection	5	Helminthic Infection	1
Hepatitis C	5	Parotitis	1
Abscess Limb	5	Pneumonia Cryptococcal	1
Lyme Disease	5	Meningitis Viral	1
Arthritis Bacterial	5	Pharyngotonsillitis	1
Otitis Externa	5	Fournier'S Gangrene	1
Peritonsillar Abscess	5	Gonorrhoea	1
Myelitis	5	Viral Myocarditis	1
Varicella Zoster Virus Infection	5	Psoas Abscess	1
Infection Reactivation	5	Oral Pustule	1
Staphylococcal Sepsis	4	Viral Pharyngitis	1
Pneumonia Aspiration	4	Tonsillitis Streptococcal	1
Vulvovaginal Candidiasis	4	Osteomyelitis Bacterial	1
Infection Susceptibility Increased	4	Gastrointestinal Viral Infection	1
Abdominal Infection	4	Proteus Infection	1
Acarodermatitis	4	Gas Gangrene	1
Root Canal Infection	4	Atypical Mycobacterial Infection	1
Gastric Infection	4	Pneumonia Necrotising	1
Abscess Oral	4	Cardiac Infection	1
Skin Candida	4	Pyoderma	1
Fungal Oesophagitis	4	Ear Infection Viral	1
Ear Infection Fungal	4	Mucosal Infection	1
Escherichia Pyelonephritis	4	Acne Pustular	1
Suspected Covid-19	4	Post Procedural Sepsis	1

Bacteraemia	3	Spinal Cord Abscess	1
Encephalitis	3	Bronchitis Viral	1
Meningitis	3	Herpes Zoster Oticus	1
Endocarditis	3	Dysentery	1
Hepatitis A	3	Biliary Tract Infection	1
Hiv Infection	3	Gastrointestinal Bacterial Overgrowth	1
Pneumonia Bacterial	3	Fusarium Infection	1
Cellulitis Staphylococcal	3	Hand-Foot-And-Mouth Disease	1
Staphylococcal Abscess	3	Tinea Versicolour	1
Clostridial Infection	3	Brucellosis	1
Cholecystitis Infective	3	Leishmaniasis	1
Rash Pustular	3	Spinal Cord Infection	1
Infectious Mononucleosis	3	Meningitis Pneumococcal	1
Breast Abscess	3	Chronic Tonsillitis	1
Pulmonary Tuberculosis	3	Cryptococcosis	1
Rectal Abscess	3	Community Acquired Infection	1
Meningitis Bacterial	3	Genital Infection Fungal	1
Arthritis Infective	3	Gallbladder Abscess	1
Paronychia	3	Meningoencephalitis Bacterial	1
Lung Abscess	3	Neurosyphilis	1
Latent Tuberculosis	3	Pneumonia Influenzal	1
Body Tinea	3	Toxic Shock Syndrome	1
Dermo-Hypodermitis	3	Cellulitis Streptococcal	1
Hepatic Infection	3	Genital Infection	1
Prostate Infection	3	Laryngitis Fungal	1
Infected Bite	3	Viral Rash	1
Mastoiditis	3	Ear Infection Bacterial	1
Injection Site Pustule	3	Adenoviral Conjunctivitis	1
Epiglottitis	3	Mucocutaneous Candidiasis	1
Oesophageal Infection	3	Systemic Infection	1
Genital Candidiasis	3	Pyoderma Streptococcal	1
Peritonitis	2	Pharyngolaryngeal Abscess	1
Cytomegalovirus Infection	2	Periorbital Abscess	1
Mastitis	2	Hookworm Infection	1
Liver Abscess	2	Coxsackie Myocarditis	1
Bacterial Vaginosis	2	Fracture Infection	1
Groin Infection	2	Fungal Pharyngitis	1
Labyrinthitis	2	Herpes Zoster Reactivation	1
Bronchopulmonary Aspergillosis	2	Herpes Zoster Meningoradiculitis	1
Vaginal Infection	2	Coronavirus Pneumonia	1
Perirectal Abscess	2	Sycosis Barbae	1
Chronic Sinusitis	2	Pitted Keratolysis	1
Pharyngitis Bacterial	2	Focal Peritonitis	1
Brain Abscess	2	Norovirus Infection	1
Pseudomonas Infection	2		
Syphilis	2		
Pneumococcal Sepsis	2		
Diarrhoea Infectious	2		
Sweat Gland Infection	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%[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.