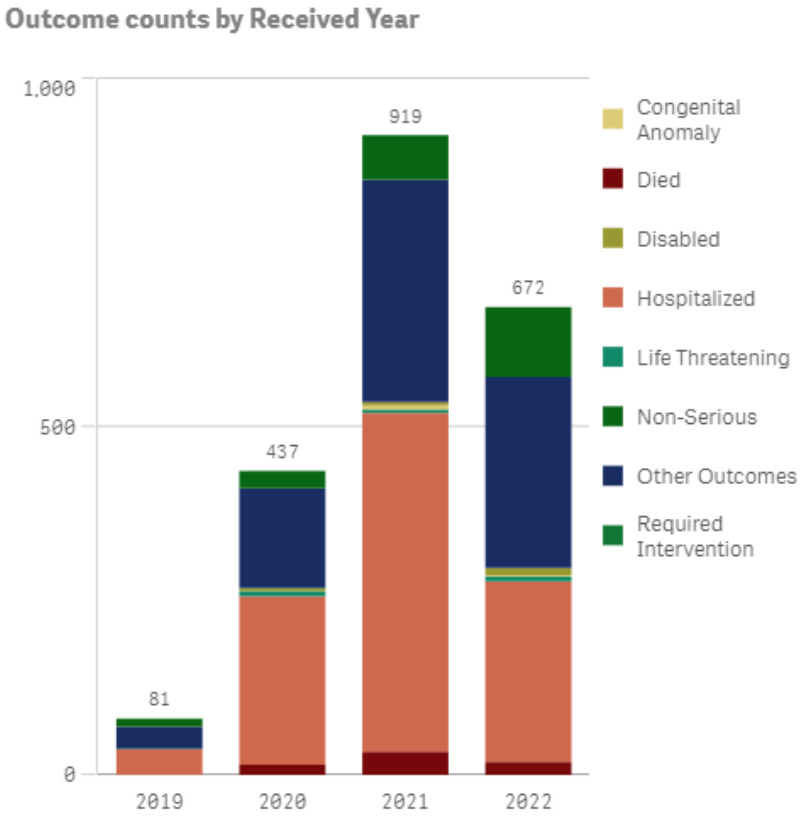
Provision of Publicly Available FAERs Data for Skyrizi® (Risankizumab)

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 Skyrizi® (Risankizumab) 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 Skyrizi please contact the manufacturer AbbVie on 1-800-633-9110.

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



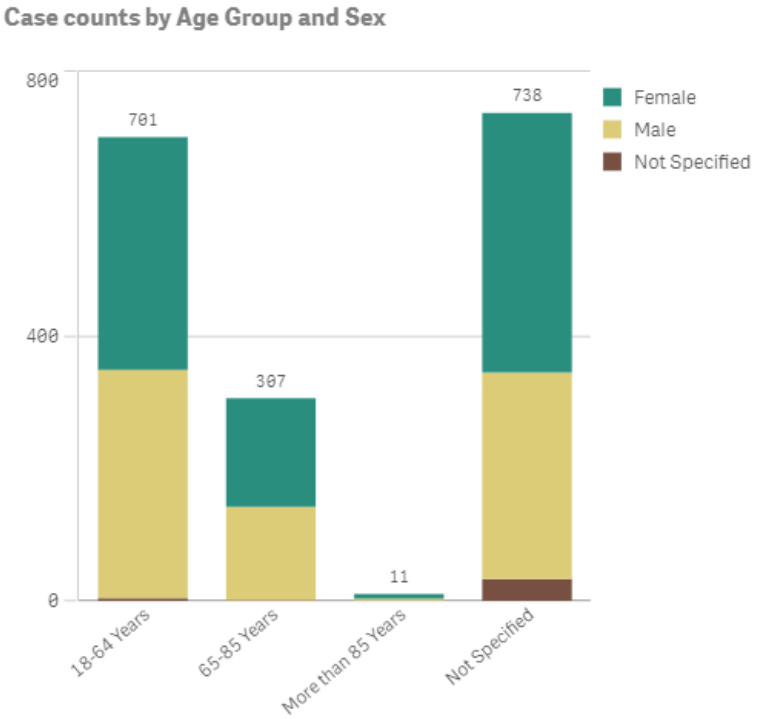


Table of Adverse Events of Infections (*Skyrizi® (Risankizumab)*) with data as of 30 June 2022

Reaction Term	Count	Reaction Term	Count
Covid-19	460	Lung Abscess	2
Pneumonia	245	Klebsiella Infection	2
Urinary Tract Infection	120	Infected Cyst	2
Infection	70	Parotitis	2
Nasopharyngitis	65	Peritonsillar Abscess	2
Sepsis	60	Hepatic Infection	2
Localised Infection	53	Nail Infection	2
Cellulitis	49	Prostate Infection	2
Staphylococcal Infection	39	Cardiac Infection	2
Sinusitis	37	Intestinal Sepsis	2
Diverticulitis	37	Post Procedural Pneumonia	2
Tuberculosis	36	Joint Abscess	2
Covid-19 Pneumonia	35	Cardiac Valve Abscess	2
Influenza	34	Prosthetic Valve Endocarditis	2
Appendicitis	32	Medical Device Site Abscess	2
Bronchitis	26	Aerococcus Urinae Infection	2
Post Procedural Infection	26	Injection Site Infection	1
Kidney Infection	22	Mastitis	1
Skin Infection	22	Bacterial Vaginosis	1
Upper Respiratory Tract Infection	21	Pneumocystis Jirovecii Pneumonia	1
Abscess	20	Parainfluenzae Virus Infection	1
Ear Infection	18	Injection Site Abscess	1
Postoperative Wound Infection	18	Labyrinthitis	1
Herpes Zoster	17	Bronchopulmonary Aspergillosis	1
Wound Infection	17	Rotavirus Infection	1
Latent Tuberculosis	16	Otitis Media	1
Bacterial Infection	15	Pneumonia Fungal	1
Fungal Infection	14	Bacterial Sepsis	1
Appendicitis Perforated	14	Gastroenteritis Norovirus	1
Coronavirus Infection	14	Hiv Infection	1
Cystitis	13	Staphylococcal Abscess	1
Urosepsis	13	Injection Site Cellulitis	1
Gastrointestinal Infection	13	Oral Candidiasis	1
Suspected Covid-19	13	Oropharyngeal Candidiasis	1
Clostridium Difficile Infection	12	Pneumonia Staphylococcal	1
Respiratory Tract Infection	11	Infection Susceptibility Increased	1
Septic Shock	10	Oral Fungal Infection	1
Device Related Infection	9	Breast Abscess	1
Arthritis Infective	9	Syphilis	1
Escherichia Infection	8	Bacterial Vulvovaginitis	1
Abscess Limb	8	Device Related Sepsis	1
Purulent Discharge	8	Hordeolum	1
Pneumonia Bacterial	8	West Nile Viral Infection	1
Genital Herpes	8	Tinea Cruris	1
Furuncle	8	Oesophageal Candidiasis	1
Fungal Skin Infection	8	Helicobacter Infection	1
Tooth Infection	8	Escherichia Sepsis	1
Rhinitis	7	Hepatitis B	1
Candida Infection	7	Urinary Tract Infection Enterococcal	1
Lower Respiratory Tract Infection	7	Pilonidal Disease	1
Pustule	7	Adenovirus Infection	1

Streptococcal Infection	7	Mycobacterium Avium Complex Infection	1
Wound Infection Staphylococcal	7	Hepatitis E	1
Botryomycosis	7	Bronchiolitis	1
Eye Infection	6	Urethritis	1
Hepatitis C	6	Body Tinea	1
Osteomyelitis	6	Epididymitis	1
Viral Infection	6	Histoplasmosis Disseminated	1
Pyelonephritis	6	Viral Upper Respiratory Tract Infection	1
Tooth Abscess	6	Ophthalmic Herpes Zoster	1
Bacteraemia	5	Overgrowth Bacterial	1
Staphylococcal Sepsis	5	Pulpitis Dental	1
Laryngitis	5	Incision Site Abscess	1
Necrotising Fasciitis	5	Opportunistic Infection	1
Rash Pustular	5	Chikungunya Virus Infection	1
Pharyngitis Streptococcal	5	Bursitis Infective	1
Infected Skin Ulcer	5	Cryptosporidiosis Infection	1
Pneumonia Viral	5	Respiratory Tract Infection Fungal	1
Folliculitis	5	Urinary Tract Infection Bacterial	1
Pharyngitis	4	Abscess Oral	1
Herpes Virus Infection	4	Dermo-Hypodermitis	1
Pneumonia Aspiration	4	Empyema	1
Arthritis Bacterial	4	Helminthic Infection	1
Cholecystitis Infective	4	Pneumonia Legionella	1
Infectious Mononucleosis	4	Pelvic Infection	1
Tonsillitis	4	Bacteriuria	1
Herpes Ophthalmic	4	Fournier'S Gangrene	1
Papilloma Viral Infection	4	Streptococcal Sepsis	1
Gastric Infection	4	Psoas Abscess	1
Abscess Intestinal	4	Pulmonary Sepsis	1
Blister Infected	4	Post Procedural Cellulitis	1
Meningitis Viral	4	Tonsillitis Streptococcal	1
Norovirus Infection	4	Cardiac Valve Vegetation	1
Peritonitis	3	Device Related Bacteraemia	1
Gastroenteritis Viral	3	Acne Pustular	1
Gangrene	3	Post Procedural Sepsis	1
Endocarditis	3	Skin Bacterial Infection	1
Gingivitis	3	Spinal Cord Abscess	1
Abdominal Abscess	3	Genital Abscess	1
Onychomycosis	3	Abscess Neck	1
Anal Abscess	3	Herpes Zoster Oticus	1
Chronic Sinusitis	3	Septic Arthritis Staphylococcal	1
Herpes Simplex	3	Gastrointestinal Bacterial Overgrowth	1
Tinea Pedis	3	Large Intestine Infection	1
Dengue Fever	3	Cutaneous Tuberculosis	1
Gastroenteritis	3	Infected Fistula	1
Acarodermatitis	3	Coccidioidomycosis	1
Erysipelas	3	Lymph Gland Infection	1
Escherichia Urinary Tract Infection	3	Propionibacterium Infection	1
Staphylococcal Bacteraemia	3	Herpes Zoster Meningoencephalitis	1
Gastroenteritis Bacterial	3	Scarlet Fever	1
Medical Device Site Infection	3	Neurosyphilis	1
Spinal Cord Infection	3	Respiratory Tract Infection Bacterial	1

Epiglottitis	3	Administration Site Infection	1
Asymptomatic Covid-19	3	Wound Infection Fungal	1
Conjunctivitis	2	Pneumonia Haemophilus	1
Liver Abscess	2	Infective Tenosynovitis	1
Subcutaneous Abscess	2	Puncture Site Infection	1
Groin Infection	2	Tinea Capitis	1
Rhinovirus Infection	2	Testicular Abscess	1
Encephalitis	2	Wound Sepsis	1
Respiratory Syncytial Virus Infection	2	Nipple Infection	1
Oral Herpes	2	Anorectal Cellulitis	1
Vulvovaginal Mycotic Infection	2	Infective Thrombosis	1
Cellulitis Staphylococcal	2	Anal Fistula Infection	1
Atypical Pneumonia	2	Haemophilus Sepsis	1
Impetigo	2	Meningoencephalitis Viral	1
Tinea Infection	2	Gallbladder Empyema	1
Pneumonia Mycoplasmal	2	Administration Site Cellulitis	1
Renal Abscess	2	Zika Virus Infection	1
Purulence	2	Myiasis	1
Rectal Abscess	2	Ebola Disease	1
Oral Infection	2	Diverticulitis Intestinal Perforated	1
Groin Abscess	2	Vibrio Vulnificus Infection	1
Paronychia	2	Shewanella Algae Bacteraemia	1
Implant Site Infection	2	Bacterial Endophthalmitis	1

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.