Provision of Publicly Available FAERs Data for Stelara® (Ustekinumab)

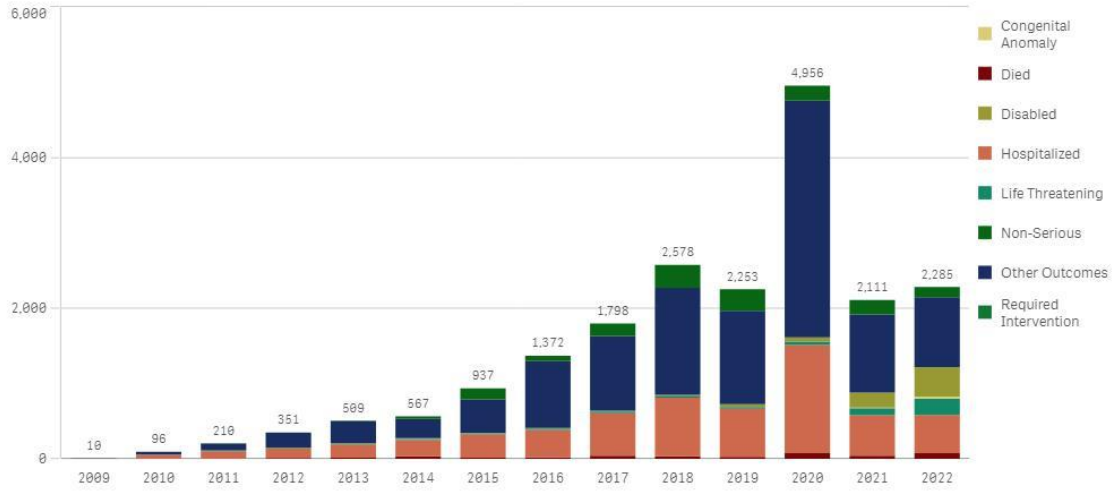
You are accessing this document as you are taking part in the Veradigm Adverse Event Deep-Dive Program, a GSK sponsored pilot program which aims to facilitate and evaluate a bi-directional communication process with a trusted third party using the Practice Fusion secure messaging system to enhance and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

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

Outcome counts by Received Year



Case counts by Age Group and Sex

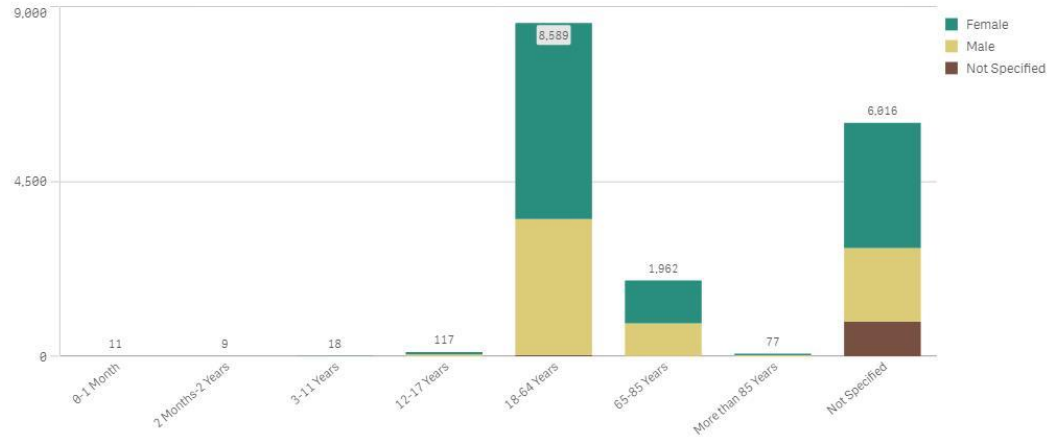


Table of Adverse Events of Infections (n≥10) (*Stelara® (Ustekinumab)*) with data as of 30 June 2022

Reaction Term	Count	Reaction Term	Count
Pneumonia	2,236	Varicella	23
Lower Respiratory Tract Infection	2,194	Oesophageal Candidiasis	23
Infection	1,246	Encephalitis	22
Nasopharyngitis	1,072	Pertussis	22
Urinary Tract Infection	783	Breast Abscess	22
Sinusitis	753	Hepatitis B Reactivation	22
Cellulitis	708	Lupus Vulgaris	22
Helicobacter Infection	637	Gingivitis	21
Influenza	564	Vulvovaginal Mycotic Infection	21
Covid-19	507	Vaginal Infection	21
Sepsis	422	Meningitis Viral	21
Bronchitis	393	Liver Abscess	20
Herpes Zoster	385	Ophthalmic Herpes Zoster	20
Clostridium Difficile Infection	358	Salmonellosis	20
Abscess	356	Pyoderma	20
Upper Respiratory Tract Infection	320	Labyrinthitis	19
Folliculitis	268	Pelvic Abscess	19
Ear Infection	264	Viral Upper Respiratory Tract Infection	19
Kidney Infection	260	Appendicitis Perforated	18
Respiratory Tract Infection	257	HIV Infection	18
Staphylococcal Infection	249	Herpes Simplex	18
Diverticulitis	248	Hordeolum	18
Anal Abscess	235	Orchitis	18
Tooth Abscess	231	Gastrointestinal Bacterial Infection	18
Tuberculosis	173	Pneumonia Aspiration	17
Wound Infection	169	Pulmonary Tuberculosis	17
Localised Infection	163	Oral Infection	17
Viral Infection	151	Staphylococcal Sepsis	16
Cystitis	149	Perirectal Abscess	16
Latent Tuberculosis	143	Stoma Site Infection	16
Post Procedural Infection	134	Fungal Skin Infection	16
Postoperative Wound Infection	127	Infected Skin Ulcer	16
Gastrointestinal Infection	124	Prostate Infection	16
Fungal Infection	123	Gastroenteritis Salmonella	15
Osteomyelitis	120	Atypical Pneumonia	15
Skin Infection	120	Impetigo	15
Pharyngitis	111	Epididymitis	15
Laryngitis	106	Soft Tissue Infection	15
Tonsillitis	105	Abscess Oral	15
Gastroenteritis	104	Pneumonia Legionella	15
Abdominal Abscess	100	Peritonsillar Abscess	15
Retinitis	100	Perineal Abscess	15
Tooth Infection	96	Genital Herpes	14
Appendicitis	93	Pyelonephritis Acute	14
Erysipelas	90	Pilonidal Disease	14
Candida Infection	81	Infective Exacerbation Of Chronic Obstructive Airways Disease	14
Oral Herpes	81	Colonic Abscess	14
Abscess Intestinal	75	Hepatic Infection	14
Abscess Limb	74	Pneumonia Pneumococcal	14

Gastroenteritis Viral	74	Varicella Zoster Virus Infection	14
Rectal Abscess	74	Histoplasmosis	14
Septic Shock	70	Otitis Media	13
Pyelonephritis	64	Epstein-Barr Virus Infection	13
Device Related Infection	63	Beta Haemolytic Streptococcal Infection	13
Bacterial Infection	63	Escherichia Sepsis	13
Pharyngitis Streptococcal	59	Abdominal Wall Abscess	13
Oral Candidiasis	58	Intervertebral Discitis	13
Hepatitis C	57	Otitis Externa	13
Subcutaneous Abscess	56	Chlamydial Infection	13
Furuncle	51	Bacterial Vaginosis	12
Pustule	51	Endocarditis	12
Eye Infection	49	Clostridial Infection	12
Escherichia Infection	49	Tinea Pedis	12
Peritonitis	46	Pseudomonas Infection	12
Gastric Infection	44	Acarodermatitis	12
Cytomegalovirus Infection	43	Bacterial Vulvovaginitis	12
Streptococcal Infection	43	Respiratory Tract Infection Viral	12
Mastitis	40	Herpes Ophthalmic	12
Herpes Virus Infection	40	Infected Bite	12
Gastroenteritis Norovirus	40	Sialoadenitis	12
Infected Fistula	39	Large Intestine Infection	12
Rhinitis	38	Pneumocystis Jirovecii Pneumonia	11
Urosepsis	38	Vulvovaginal Candidiasis	11
Suspected Covid-19	37	Bacillus Infection	11
Covid-19 Pneumonia	37	Cytomegalovirus Colitis	11
Meningitis	35	Periodontitis	11
Conjunctivitis	34	Histoplasmosis Disseminated	11
Infected Cyst	34	Infection Parasitic	11
Bacteraemia	33	External Ear Cellulitis	11
Onychomycosis	33	Purulent Discharge	10
Coronavirus Infection	33	Chronic Sinusitis	10
Lyme Disease	32	Oral Fungal Infection	10
Staphylococcal Bacteraemia	32	Amniotic Cavity Infection	10
Arthritis Bacterial	31	Root Canal Infection	10
Rash Pustular	31	Paronychia	10
Vascular Device Infection	30	Staphylococcal Skin Infection	10
Groin Abscess	30	Nail Infection	10
Hepatitis B	30	Skin Candida	10
Chikungunya Virus Infection	30	Lower Respiratory Tract Infection Bacterial	10
Postoperative Abscess	29	Septic Arthritis Staphylococcal	10
Cholecystitis Infective	28	Coccidioidomycosis	10
Abdominal Infection	28	Vulval Abscess	10
Clostridium Difficile Colitis	27		
Pneumonia Bacterial	26		
Dengue Fever	26		
Escherichia Urinary Tract Infection	26		
Papilloma Viral Infection	26		
Infectious Mononucleosis	25		
Arthritis Infective	24		
Gangrene	23		

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.