

## Provision of Publicly Available FAERs Data for Cosentyx® (Secukinumab)

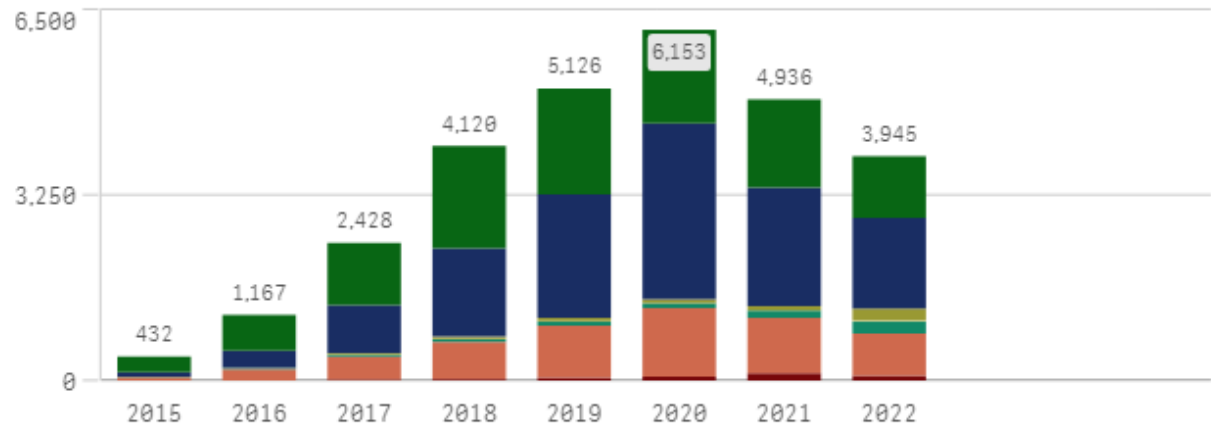
You are accessing this document as you are taking part in the Veradigm Adverse Event Deep-Dive Program, a GSK sponsored pilot program which aims to facilitate and evaluate a bi-directional communication process with a trusted third party using the Practice Fusion secure messaging system to enhance and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

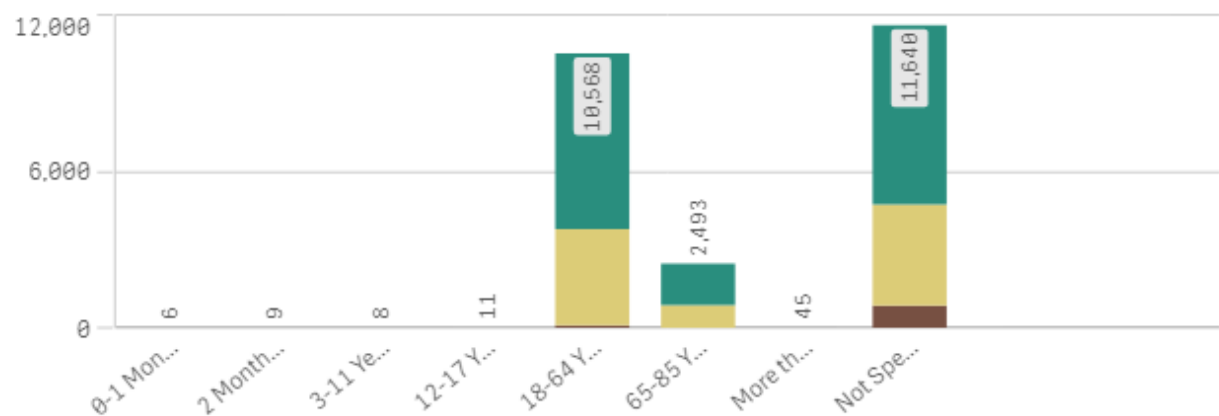
The information provided below is for **information purposes only**, when using this data, you should be aware that there are a number of limitations, these are described in detail in this document and available on the FAERs public dashboard website. If you have any questions related to Cosentyx please contact the manufacturer Novartis on 1-888-669-6682.

**Pre-filtered to Cosentyx® (Secukinumab) 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) (Cosentyx® (Secukinumab)) with data as of 30 June 2022**

| Reaction Term                     | Count | Reaction Term                           | Count |
|-----------------------------------|-------|---|-------|
| Nasopharyngitis                   | 3,993 | Ear Infection Fungal                    | 27    |
| Pneumonia                         | 2,192 | Genital Candidiasis                     | 27    |
| Covid-19                          | 2,101 | Abdominal Abscess                       | 26    |
| Infection                         | 2,054 | Bursitis Infective                      | 26    |
| Influenza                         | 2,024 | Skin Candida                            | 26    |
| Sinusitis                         | 1,930 | Oesophageal Infection                   | 25    |
| Urinary Tract Infection           | 1,439 | Infectious Mononucleosis                | 24    |
| Lower Respiratory Tract Infection | 1,261 | Infected Cyst                           | 24    |
| Bronchitis                        | 1,015 | Chronic Sinusitis                       | 23    |
| Cellulitis                        | 866   | Bacterial Vaginosis                     | 22    |
| Upper Respiratory Tract Infection | 862   | Abdominal Infection                     | 22    |
| Ear Infection                     | 613   | Pneumonia Viral                         | 22    |
| Herpes Zoster                     | 545   | Viral Upper Respiratory Tract Infection | 22    |
| Fungal Infection                  | 526   | Clostridium Difficile Colitis           | 21    |
| Candida Infection                 | 453   | Genital Herpes                          | 21    |
| Localised Infection               | 428   | Peritonitis                             | 20    |
| Staphylococcal Infection          | 425   | Varicella                               | 20    |
| Oral Candidiasis                  | 419   | Sialoadenitis                           | 20    |
| Sepsis                            | 417   | Fungal Oesophagitis                     | 20    |
| Viral Infection                   | 399   | Infected Dermal Cyst                    | 20    |
| Respiratory Tract Infection       | 385   | Bacteraemia                             | 19    |
| Cystitis                          | 384   | Gangrene                                | 19    |
| Diverticulitis                    | 358   | Staphylococcal Sepsis                   | 19    |
| Pharyngitis Streptococcal         | 331   | Helicobacter Gastritis                  | 19    |
| Kidney Infection                  | 306   | Pulmonary Tuberculosis                  | 19    |
| Oral Herpes                       | 283   | Papilloma Viral Infection               | 19    |
| Pharyngitis                       | 281   | Myelitis                                | 19    |
| Helicobacter Infection            | 266   | Campylobacter Gastroenteritis           | 19    |
| Tuberculosis                      | 250   | Pneumocystis Jirovecii Pneumonia        | 18    |
| Tooth Abscess                     | 243   | Pulpitis Dental                         | 18    |
| Tonsillitis                       | 240   | Abscess Oral                            | 18    |
| Laryngitis                        | 212   | Peritonsillar Abscess                   | 18    |
| Skin Infection                    | 200   | Prostate Infection                      | 18    |
| Eye Infection                     | 184   | Dysentery                               | 18    |
| Bacterial Infection               | 183   | Gastrointestinal Fungal Infection       | 18    |
| Wound Infection                   | 182   | Groin Infection                         | 17    |
| Tooth Infection                   | 179   | Necrotising Fasciitis                   | 17    |
| Erysipelas                        | 177   | Staphylococcal Bacteraemia              | 17    |
| Folliculitis                      | 175   | Gastrointestinal Bacterial Infection    | 17    |
| Gastroenteritis Viral             | 173   | Liver Abscess                           | 16    |
| Rhinitis                          | 173   | Pseudomonas Infection                   | 16    |
| Conjunctivitis                    | 169   | Pathogen Resistance                     | 16    |
| Furuncle                          | 169   | Fungal Pharyngitis                      | 16    |
| Coronavirus Infection             | 143   | Mastitis                                | 15    |
| Pustule                           | 142   | Staphylococcal Abscess                  | 15    |
| Abscess                           | 134   | Beta Haemolytic Streptococcal Infection | 15    |
| Osteomyelitis                     | 129   | Wound Infection Staphylococcal          | 15    |
| Gastroenteritis                   | 118   | Gingival Abscess                        | 15    |
| Streptococcal Infection           | 109   | Tonsillitis Bacterial                   | 15    |
| Oesophageal Candidiasis           | 100   | Lupus Vulgaris                          | 15    |

|   |    |                                       |    |
|---|----|---------------------------------------|----|
| Gastrointestinal Infection              | 98 | Respiratory Syncytial Virus Infection | 14 |
| Abscess Limb                            | 96 | Tinea Infection                       | 14 |
| Pyelonephritis                          | 93 | Purulence                             | 14 |
| Clostridium Difficile Infection         | 87 | Tinea Cruris                          | 14 |
| Tinea Pedis                             | 87 | Lung Abscess                          | 14 |
| Vaginal Infection                       | 85 | Bronchiolitis                         | 14 |
| Post Procedural Infection               | 83 | Oral Pustule                          | 14 |
| Suspected Covid-19                      | 80 | Skin Bacterial Infection              | 14 |
| Arthritis Infective                     | 79 | Tinea Versicolour                     | 14 |
| Covid-19 Pneumonia                      | 75 | Mucocutaneous Candidiasis             | 14 |
| Postoperative Wound Infection           | 73 | Gastroenteritis Norovirus             | 13 |
| Appendicitis                            | 70 | Mumps                                 | 13 |
| Septic Shock                            | 70 | Orchitis                              | 13 |
| Onychomycosis                           | 69 | Intervertebral Discitis               | 13 |
| Herpes Virus Infection                  | 64 | Epididymitis                          | 13 |
| Oral Fungal Infection                   | 63 | Conjunctivitis Viral                  | 13 |
| Subcutaneous Abscess                    | 59 | Large Intestine Infection             | 13 |
| Oral Infection                          | 58 | Fungal Foot Infection                 | 13 |
| Retinitis                               | 55 | Balanitis Candida                     | 13 |
| Rash Pustular                           | 54 | Cellulitis Staphylococcal             | 12 |
| Latent Tuberculosis                     | 54 | Pertussis                             | 12 |
| Arthritis Bacterial                     | 52 | Acarodermatitis                       | 12 |
| Vulvovaginal Candidiasis                | 51 | Pyelonephritis Acute                  | 12 |
| Purulent Discharge                      | 50 | Infected Skin Ulcer                   | 12 |
| Lower Respiratory Tract Infection Viral | 50 | Measles                               | 12 |
| Infection Susceptibility Increased      | 49 | Respiratory Tract Infection Viral     | 12 |
| Gastric Infection                       | 47 | Ophthalmic Herpes Zoster              | 12 |
| Impetigo                                | 46 | Salmonellosis                         | 12 |
| Gingivitis                              | 45 | Parotitis                             | 12 |
| Herpes Simplex                          | 45 | Histoplasmosis                        | 12 |
| Lyme Disease                            | 43 | Pyoderma                              | 12 |
| Fungal Skin Infection                   | 42 | Acne Pustular                         | 12 |
| Vulvovaginal Mycotic Infection          | 41 | Genital Abscess                       | 12 |
| Hepatitis C                             | 40 | Abscess Neck                          | 12 |
| Otitis Media                            | 40 | Endocarditis                          | 11 |
| Escherichia Infection                   | 39 | Pharyngitis Bacterial                 | 11 |
| Dengue Fever                            | 39 | Gastrointestinal Candidiasis          | 11 |
| Device Related Infection                | 38 | Breast Abscess                        | 11 |
| Labyrinthitis                           | 38 | Soft Tissue Infection                 | 11 |
| Anal Abscess                            | 37 | Hepatitis B Reactivation              | 11 |
| Atypical Pneumonia                      | 35 | Empyema                               | 11 |
| Pneumonia Aspiration                    | 34 | Lymph Gland Infection                 | 11 |
| Hordeolum                               | 34 | Leprosy                               | 11 |
| Otitis Externa                          | 33 | Injection Site Infection              | 10 |
| Staphylococcal Skin Infection           | 33 | Encephalitis                          | 10 |
| Pneumonia Bacterial                     | 31 | Hepatitis A                           | 10 |
| Paronychia                              | 31 | Hiv Infection                         | 10 |
| Escherichia Urinary Tract Infection     | 30 | Nosocomial Infection                  | 10 |
| Urosepsis                               | 29 | Systemic Candida                      | 10 |
| Oropharyngeal Candidiasis               | 29 | Herpes Ophthalmic                     | 10 |
| Hepatitis B                             | 29 | Lymphangitis                          | 10 |
| Meningitis                              | 27 | Pneumonia Pneumococcal                | 10 |
| Cholecystitis Infective                 | 27 | Varicella Zoster Virus Infection      | 10 |
| Groin Abscess                           | 27 | Meningitis Streptococcal              | 10 |
| Urinary Tract Infection Bacterial       | 27 | Genital Infection Fungal              | 10 |
| Nail Infection                          | 27 |                                       |    |

## **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.