

From: Marks, Peter
Sent: Thu, 6 Jan 2022 21:46:27 +0000
To: Remley, Karen (CDC/DDNID/NCBDDD/OD); Walensky, Rochelle (CDC/OD); Oliver, Sara Elizabeth (CDC/DDID/NCIRD/DVD)
Subject: EUA Amendment
Attachments: Moderna Booster Expansion Amendment Review FINAL.pdf, FINAL - Janssen Hetero Review Memorandum Addendum #3.pdf, FINAL - Pfizer Hetero Review Memorandum Addendum #2 (002).pdf

Dear Rochelle, Sara, and Karen,

Sharing tomorrow's action memos on the Moderna 6 to 5 month booster change. Please hold strictly confidential until after our press release in the AM. Thank you!

Best Regards,
Peter

Produced to Homeland Security and Government Affairs Permanent Subcommittee on Investigations Pursuant to Oversight Request
Do Not Disclose Without Permission from U.S. Department of Health and Human Services



Review Memorandum

Date: January 6, 2022

To: The File

From: Peter Marks, MD, PhD (CBER/OD) Peter W. Marks -S

Applicant name: ModernaTX, Inc.

Application Number: EUA 27073

Product: Moderna COVID-19 Vaccine

Subject: CBER assessment of a single booster dose of the Moderna COVID-19 Vaccine (0.25 mL) administered at 5 months

This memorandum provides a summary, review, and recommendation to amend the emergency use authorization (EUA) of the Moderna COVID-19 Vaccine to allow the administration of a single homologous booster dose to individuals 18 years of age or older, at least 5 months after completion of a primary series of the Moderna COVID-19 Vaccine (i.e., as a homologous booster dose), and to authorize use of the Moderna COVID-19 Vaccine as a single booster dose following completion of primary vaccination with another authorized or approved COVID-19 vaccine (i.e., as a heterologous booster dose) in individuals 18 years of age or older. The dosing interval for the heterologous booster dose is the same as that authorized for a booster dose of the vaccine used for primary vaccination.

Executive Summary

The Moderna COVID-19 Vaccine's currently authorized indication is for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 18 years of age and older. It is authorized for use as a 2-dose primary series, each dose being 100 µg mRNA (0.5 mL), in individuals 18 years of age and older and as a third primary series dose of 100 µg mRNA (0.5 mL) for use in individuals 18 years of age and older with certain immunocompromising conditions. A single booster dose of 50 µg mRNA (0.25 mL) of the Moderna COVID-19 Vaccine is authorized for use in individuals 18 years of age and older following completion of a primary series of the Moderna COVID-19 Vaccine (homologous booster) or for those 18 years of age and older following completion of primary vaccination with another FDA-authorized COVID-19 vaccine (heterologous booster). The authorized interval between completion of primary vaccination and booster dose for a Moderna COVID-19 Vaccine homologous booster is currently at least 6 months, and for a heterologous booster is the same as that authorized for a booster dose of the vaccine used for primary vaccination.

On December 1, 2021, the first confirmed case of the SARS-CoV-2 variant Omicron (B.1.1.529) was identified in the United States. Since that time, the proportion of cases due to the Omicron variant is estimated to have increased to be over 50% and is rising. This rapid increase in the proportion of cases



attributable to the Omicron variant, relative to the previously highly prevalent SARS-CoV-2 variant Delta (B.1.617.2), is contemporaneous with a surge in COVID-19 cases in the United States. Laboratory data indicate that the Omicron variant is more resistant to neutralization by the antibodies generated with the currently available COVID-19 vaccines, and that a third mRNA vaccine dose may provide improved protection against the Omicron variant. In this context, the current action allows the administration of a single homologous booster dose of the Moderna COVID-19 Vaccine (to individuals 18 years of age and older at least 5 months after completion of a primary series. A single 50 µg booster dose of the Moderna COVID-19 Vaccine (0.25 mL) may be administered to individuals 18 years of age and older as a heterologous booster dose following completion of primary vaccination with another authorized or approved COVID-19 vaccine.¹ The dosing interval for the heterologous booster dose is the same as that authorized for a booster dose of the vaccine used for primary vaccination.

Data previously provided by the sponsor indicated that a 50 µg (0.25 mL) booster dose of the Moderna COVID-19 Vaccine administered to individuals 18 years of age and older at least 6 months following completion of a 2-dose primary series resulted in a neutralizing antibody geometric mean titer ratio of 1.8-fold for the geometric mean titer one month after the booster dose relative to the geometric mean titer one month after completion of the primary series. Additional immunogenicity data supported activity of neutralizing antibodies elicited by the vaccine against the SARS-CoV-2 Delta variant.

Data reviewed in support of the current action include information provided by the sponsor in its request submitted on January 4, 2022, that following a booster dose of their vaccine administered after the 2-dose primary series, neutralization capacity for the Omicron variant is reduced by half in 57 days. The sponsor also references a study conducted by the National Institute of Allergy and Infectious Disease in a total of 154 individuals who received a 100 µg booster dose between 12.0 and 20.9 weeks following completion of the primary series of either Moderna, Pfizer-BioNTech, or Janssen COVID-19 vaccines with good immunogenicity and no observed safety concerns. Though obtained with a different mRNA vaccine, additional relevant data reviewed by the agency includes that from the Ministry of Health of Israel indicating no new safety concerns in 4.1 million individuals age 16 years and older who received the Pfizer-BioNTech COVID-19 Vaccine series with booster doses administered at least 5 months following completion of the primary series. Although the overall composition of the Moderna COVID-19 Vaccine is different than the Pfizer-BioNTech COVID-19 Vaccine, both are mRNA vaccines with safety and efficacy profiles that, though not identical, are relatively similar. Acknowledging the differences, it is reasonable to make the inference that the safety data on the 5 month interval for booster doses obtained in the population in Israel can apply to the Moderna COVID-19 Vaccine.

Based on an assessment of benefits and risks informed by available data, FDA has concluded that the data support the administration of a single homologous booster dose of 50 µg (0.25 mL) of the Moderna COVID-19 Vaccine to individuals 18 years of age or older, at least 5 months after completion of a primary series of this vaccine (i.e., as a homologous booster dose), and to authorize use of the vaccine as a single booster dose following completion of primary vaccination with another authorized or approved COVID-19 vaccine (i.e., as a heterologous booster dose) in individuals 18 years of age or older. The dosing interval for the heterologous booster dose is the same as that authorized for a booster dose of the vaccine used for primary vaccination..

Review

Disease Background

SARS-CoV-2 is a zoonotic coronavirus that emerged in late 2019 and was identified in patients with pneumonia of unknown cause. The virus was named SARS-CoV-2 because of its similarity to the coronavirus responsible for severe acute respiratory syndrome (SARS-CoV, a lineage B betacoronavirus). SARS-CoV-2 is an enveloped, positive-sense, single-stranded RNA virus sharing more than 70% of its sequence with SARS-CoV, and ~50% with the coronavirus responsible for Middle Eastern respiratory syndrome (MERS-CoV). SARS-CoV-2 is the causative agent of COVID-19, an infectious disease with respiratory and systemic manifestations. Disease symptoms vary, with many persons presenting with asymptomatic or mild disease and some progressing to severe respiratory tract disease including pneumonia and acute respiratory distress syndrome (ARDS), leading to multiorgan failure and death.

The SARS-CoV-2 pandemic continues to present a challenge to global health and, as of January 4, 2022, has caused approximately 282 million cases of COVID-19, including over 5.4 million deaths worldwide. In the United States, more than 53.7 million cases and 820,000 deaths have been reported to the Centers for Disease Control and Prevention (CDC). While the pandemic has caused morbidity and mortality on an individual level, the continuing spread of SARS-CoV-2, and emerging variants (such as the very highly transmissible Omicron variant that is now rapidly spreading and predominant in the United States) have caused significant challenges and disruptions in worldwide healthcare systems, economies, and many aspects of human activity (travel, employment, education).

Following EUA of COVID-19 vaccines in December 2020, COVID-19 cases and deaths in the United States declined sharply during the first half of 2021. The emergence of the Delta (B.1.617.2) and Omicron (B.1.1.529) variants and their rapid spread across the globe, variable implementation of public health measures designed to control spread, and continued transmission among unvaccinated individuals are major factors in the recent resurgence of COVID-19. Although the number of COVID-19 cases appeared to be declining in October 2021 relative to the Delta variant-associated peak globally and in the United States, during the months of November and December 2021 there was a marked increase in cases in Western Europe and the number of cases in the United States increased starting in early November 2021.

Of particular concern, the Omicron variant was initially identified in the Republic of South Africa in November 2021, with subsequent detection worldwide. On December 1, 2021, the first confirmed case of the Omicron variant was identified in the United States. Since that time, the proportion of cases due to the Omicron variant in the United States is estimated to be over 50% of the COVID-19 cases and appears to be increasing (<https://covid.cdc.gov/covid-data-tracker/#variant-proportions>). This rapid increase in the proportion of cases attributable to the Omicron variant, relative to the previously highly prevalent Delta variant, is contemporaneous with a surge in COVID-19 cases in the United States.

Although data continue to emerge on a daily basis, the full significance of the Omicron variant has recently become more clear. This variant appears to be highly transmissible, with a reproductive number that appears to be several times higher than that for the Delta variant (Nishiura H, Ito K, Anzai A, et al., Relative reproductive number of SARS-CoV-2 Omicron (B.1.1.529) compared with Delta variant in South



[Africa, J Clin Med, 2022; 11:30](#)). Additionally, both laboratory and clinical data indicate that the Omicron variant appears to be significantly more resistant to neutralization by antibodies developed to the prototype Wuhan strain of SARS-CoV-2, and this variant has been associated with breakthrough infections even in fully vaccinated individuals (Cao Y, Wang J, Jian F, et al. Omicron escapes the majority of existing SARS CoV-2 neutralizing antibodies, Nature 2021, in press, <https://doi.org/10.1038/d41586-02103796-6>; Branal LT, MacDonald E, Veneti L et al., Outbreak caused by the SARS-CoV-2 Omicron variant in Norway, November to December 2021, Euro Surveill, 2021, <https://doi.org/10.2807/1560-7917.ES.2021.26.50.2101147>). Based on the available evidence, it appears that the primary series of the COVID-19 vaccines currently available in the United States does reduce the risk of serious disease, including hospitalization and death, from the Omicron variant, and the recent administration of a booster dose of a COVID-19 vaccine appears to be associated with an even lower likelihood of breakthrough infection.

The Moderna COVID-19 Vaccine for the Prevention of COVID-19

On December 18, 2020, FDA issued an EUA for the Moderna COVID-19 Vaccine (also known as mRNA-1273), for active immunization to prevent COVID-19 due to SARS-CoV-2 in individuals 18 years of age and older. The vaccine is based on the SARS-CoV-2 spike glycoprotein antigen encoded by modified mRNA and formulated in lipid particles. The authorized regimen is a 2-dose primary vaccination series administered 1 month apart, with each dose (0.5 mL) containing 100 µg mRNA. Issuance of the EUA was based on a finding of vaccine efficacy (VE) of 94.1% compared to placebo against confirmed COVID-19 at least 14 days after completion of the 2-dose vaccination regimen and a favorable benefit/risk balance based on review of the safety data, in a study (P301) of approximately 30,000 participants with a median follow-up of 2 months after completion of the vaccination regimen.

On August 12, 2021, FDA amended the Moderna COVID-19 Vaccine EUA to authorize an additional dose to be given to certain immunocompromised individuals. On October 20, 2021, the FDA amended the Moderna COVID-19 Vaccine EUA to authorize a single booster dose (0.25 mL) containing 50 µg mRNA of the Moderna COVID-19 Vaccine administered at least 6 months after completion of a primary series to individuals 65 years of age and older, individuals 18 through 64 years of age at high risk of severe COVID-19, and individuals 18 through 64 years of age with frequent institutional or occupational exposure to SARS-CoV-2.

On November 19, 2021, the FDA amended the Moderna COVID-19 Vaccine to authorize use of the vaccine as a single booster dose in individuals 18 years of age or older, at least 6 months after completing the primary series of this vaccine (i.e., as a homologous booster dose), and to authorize use of the vaccine as a single booster dose following completion of primary vaccination with another authorized or approved COVID-19 vaccine (i.e., as a heterologous booster dose) in individuals 18 years of age or older. The dosing interval for the heterologous booster dose is the same as that authorized for a booster dose of the vaccine used for primary vaccination.

Findings from Post-EUA Surveillance: Myocarditis and Pericarditis

Post-EUA safety surveillance reports received by FDA and CDC identified increased risks of myocarditis and pericarditis, particularly within 7 days following administration of the second dose of a 2-dose primary



series of an mRNA vaccine. Reporting rates for medical chart-confirmed myocarditis and pericarditis in VAERS have been higher among males under 40 years of age than among females and older males and for Moderna COVID-19 Vaccine have been highest in males 18 through 24 years of age (approximately 38.5 cases per million second primary series doses as per CDC presentation to VRBPAC on October 26, 2021). While the rates of myocarditis reported in VAERS following the Moderna COVID-19 Vaccine are similar to those reported following the Pfizer-BioNTech COVID-19 Vaccine in corresponding age groups, some, but not all, observational analyses of postmarketing data suggest that there may be an increased risk of myocarditis and pericarditis in males under 40 years of age following the second dose of the Moderna COVID-19 Vaccine relative to the Pfizer-BioNTech COVID-19 Vaccine (see [November 19, 2021 FDA Review Memorandum](#) for additional details). The FDA analyzed data from four administrative claims databases in the Biologics Effectiveness and Safety (BEST) system to estimate the adjusted incidence rate of myocarditis and/or pericarditis per million person-days following receipt of the Moderna COVID-19 Vaccine. For males 18 through 25 years of age, the incidence rate per million person-days within one to seven days after the second dose was 18.26 (95% CI: 9.68–34.46).

Although some cases of vaccine-associated myocarditis and pericarditis have required intensive care support, available data from short-term follow-up suggest that most individuals have had resolution of symptoms with conservative management. Information is not yet available about potential long-term sequelae and outcomes in affected individuals, or whether the vaccine might be associated initially with subclinical myocarditis (and if so, what are the long-term sequelae). A mechanism of action by which the vaccine could cause myocarditis and pericarditis has not been established. On June 25, 2021, myocarditis and pericarditis were added as important identified risks in the pharmacovigilance plan and included in the Warnings sections of the vaccine Fact Sheets and EUA Prescribing Information. The sponsor is conducting additional post-authorization/post-marketing studies to assess known serious risks of myocarditis and pericarditis as well as to identify an unexpected serious risk of subclinical myocarditis.

The most recent [safety data from the Ministry of Health of Israel](#) indicate a rate of myocarditis and pericarditis in the overall population of those 16 years of age and older administered the Pfizer-BioNTech COVID-19 Vaccine following a booster dose given at least 5 months following the primary vaccination series that is about 1/3 that of the rate seen following the second vaccine dose. Although the overall composition of the Moderna COVID-19 Vaccine is different than the Pfizer-BioNTech COVID-19 Vaccine, both are mRNA vaccines with safety and efficacy profiles that, though not identical, are relatively similar. Acknowledging the differences between the two different vaccines, it is still reasonable to make the inference that the safety data on the 5 month interval for booster doses obtained in the population in Israel can apply to the Moderna COVID-19 Vaccine.

Need for the Expansion of Booster Doses

Concerns have been raised that declining neutralizing antibody titers or reduced effectiveness against symptomatic disease may herald significant declines in effectiveness against severe disease. The recent emergence of the highly transmissible Delta and Omicron variants of SARS-CoV-2 have resulted in a new wave of COVID-19 cases in many parts of the world and have led to considerations for administration of booster doses to individuals who have already received primary vaccination in an effort to enhance immunity, and thus sustain protection from COVID-19.



In particular, the very large number of recent cases of the Omicron variant is also raising significant concerns, as data indicate that due to the large number of mutations present it escapes neutralization by a variety of monoclonal antibodies and is more resistant to vaccine-induced immunity (Planas D, Saunders N, Maes P, et al., Considerable escape of SARS-CoV-2 Omicron to antibody neutralization, *Nature*, 2021, in press, <https://doi.org/10.1038/d41586-021-03827-2>). In this study by Planas and colleagues, a booster dose of the Pfizer-BioNTech COVID-19 Vaccine, as well as primary vaccination of previously infected individuals, strongly increased overall levels of anti-SARS-CoV-2 neutralizing antibodies above a threshold allowing inhibition of the Omicron variant. This finding appears to be relatively robust, as other studies have come to very similar conclusions regarding the potential benefit of a booster dose of the mRNA vaccines (Garcia-Beltran WF, St. Dennis KJ, Hoelzemer A, et al., mRNA-based COVID-19 boosters induce neutralizing immunity against SARS-CoV-2 Omicron variant, *Cell*, in press, <https://doi.org/10.1016/j.cell.2021.12.033>; Nemet I, Kliker L, Lustig Y et al., Third BNT162b2 Vaccination Neutralization of SARS-CoV-2 Omicron Infection, *N Engl J Med*, in press, <http://doi.org/10.1056/NEJMc2119358>). The totality of available evidence from these and other sources suggests that vaccinated individuals who have completed a primary series and received a subsequent booster with the Pfizer-BioNTech COVID-19 Vaccine are more likely to be better protected against symptomatic infection with the Omicron variant, and especially against severe disease.

Given the potential benefit of a booster dose in providing additional protection against disease due to the rapidly spreading Omicron variant, it is reasonable at this time to expand the use of booster doses to the fullest extent that is scientifically justified.² This would include reduction in the booster interval, which for operational efficiency would ideally be aligned between the two authorized or approved mRNA COVID-19 vaccines.

Requirements for EUA

The EUA process allows the Secretary of the United States Department of Health and Human Services (HHS), in appropriate circumstances, to declare that EUAs are justified for products to respond to certain types of threats. On February 4, 2020, pursuant to section 564 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act), the Secretary of HHS determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes COVID-19.³ On the basis of such determination, on March 27, 2020, the Secretary then declared that circumstances exist justifying the authorization of emergency use of drugs and biological products during the COVID-19 pandemic, pursuant to section 564(b)(1) of the FD&C Act.⁴

Under section 564(c) of the FD&C Act, FDA may issue an EUA during the COVID-19 pandemic after FDA concludes that the following statutory requirements are met:

² On January 3, 2022, the EUA of the Pfizer-BioNTech COVID-19 Vaccine was amended to allow the administration of a single homologous booster dose (or heterologous booster dose as authorized for another COVID-19 vaccine) to individuals 18 years of age and older at least 5 months after completion of a primary series of the Pfizer-BioNTech COVID-19 Vaccine

³ HHS, Determination of Public Health Emergency, 85 FR 7316, February 7, 2020, <https://www.federalregister.gov/documents/2020/02/07/2020-02496/determination-of-public-health-emergency>.

⁴ HHS, Emergency Use Authorization Declaration, 85 FR 18250, April 1, 2020, <https://www.federalregister.gov/documents/2020/04/01/2020-06905/emergency-use-authorization-declaration>.



- The agent referred to in the March 27, 2020 EUA declaration by the Secretary of HHS (SARS-CoV-2) can cause a serious or life-threatening disease or condition.
- Based on the totality of scientific evidence available, including data from adequate and well-controlled trials, if available, it is reasonable to believe that the product may be effective to prevent, diagnose, or treat such serious or life-threatening disease or condition that can be caused by SARS-CoV-2, or to mitigate a serious or life-threatening disease or condition caused by an FDA-regulated product used to diagnose, treat, or prevent a disease or condition caused by SARS-CoV-2.
- The known and potential benefits of the product, when used to diagnose, prevent, or treat the identified serious or life-threatening disease or condition, outweigh the known and potential risks of the product.
- There is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating the disease or condition.⁵

If these criteria are met, under an EUA, FDA can authorize unapproved medical products (or unapproved uses of approved medical products) to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by threat agents. FDA has been providing regulatory advice to COVID-19 vaccine manufacturers regarding the data needed to determine that the known and potential benefits of a booster dose outweigh the known and potential risks.

Data on a Single Booster Dose in Individuals 18 Years and Older

On January 4, 2022, ModernaTX, Inc. submitted a request to reduce the interval for the administration of a booster dose of the Moderna COVID-19 Vaccine from 6 to 5 months following the completion of primary series. Data previously provided by the sponsor indicated that a 50 µg booster dose (0.25 mL) of the Moderna COVID-19 Vaccine administered to individuals 18 years of age and older at least 6 months following completion of a 2-dose primary series resulted in a neutralizing antibody geometric mean titer ratio of 1.8-fold for the geometric mean titer one month after the booster dose relative to the geometric mean titer one month after completion of the primary series. Additional immunogenicity data supported activity of neutralizing antibodies elicited by the vaccine against the SARS-CoV-2 Delta variant.

Data reviewed in support of the current action includes information provided by the sponsor that following a booster dose of their vaccine administered after the 2-dose primary series, neutralization capacity for the Omicron variant is reduced by half in 57 days. The sponsor also references the study conducted by the National Institute of Allergy and Infectious Disease in a total of 154 individuals who received a booster dose of the Moderna vaccine between 12.0 and 20.9 weeks following completion of the primary series of the Moderna, Pfizer-BioNTech or Janssen COVID-19 vaccines with good immunogenicity and no observed safety concerns.

Two publications have documented the effectiveness in a real-world setting of booster doses administered in Israel after at least 5 months after completion of the primary series with the Pfizer-BioNTech COVID-19 Vaccine ([Arbel R, Hammerman A, Sergienko R et al., BNT162b2 vaccine booster and mortality due to](#)

⁵ Although COMIRNATY is approved to prevent COVID-19 in individuals 16 years of age and older, there are no COVID-19 vaccines that are approved for use in individuals younger than 16 or to provide homologous or heterologous booster doses.



Covid-19, N Engl J Med 2021; 385:2413-20; Bar-On YM, Goldberg Y, Mandel M, et al., Protection against Covid-19 by BNT162b2 booster across age groups, N Engl J Med 2021; 385:2421-30). The most recent safety data available as of December 15, 2021, from the Ministry of Health of Israel based upon over 4.1 million booster doses administered at least 5 months after completion of the primary series indicate a rate of myocarditis and pericarditis in the overall population of those 16 years of age and older that is about 1/3 that of the rate seen following the second vaccine dose. Although the overall composition of the Moderna COVID-19 Vaccine is different than the Pfizer-BioNTech COVID-19 vaccine, both are mRNA vaccines with safety and efficacy profiles that, though not identical, are relatively similar. Acknowledging the differences, it is reasonable to make the inference that the safety data on the 5 month interval for booster doses obtained in the population in Israel can apply to the Moderna COVID-19 Vaccine.

Additionally, use of heterologous booster doses with the Moderna COVID-19 Vaccine noted above was previously evaluated and presented at the October 15, 2021 VRBPAC meeting. As noted at the meeting, the median booster interval for the 49 individuals receiving the Moderna COVID-19 Vaccine boosted with the Janssen COVID-19 Vaccine was 19.3 weeks (range 12.6 – 26.0); the median booster interval for the 51 individuals receiving the Moderna COVID-19 Vaccine boosted with the Pfizer-BioNTech COVID-19 Vaccine was 22.9 weeks (range 12.6 – 28.7). The data presented support the authorization of heterologous booster doses of the Janssen or Pfizer COVID-19 vaccine in individuals older than 18 years of age at least 5 months following a primary series of the Moderna COVID-19 Vaccine.

Recommendation

Based on the totality of evidence submitted by the sponsor, the literature, and the Ministry of Health of Israel, and in accordance with established FDA guidance, the review team concludes that the known and potential benefits outweigh the known and potential risks, and therefore recommends the following amendments of the Moderna COVID-19 Vaccine emergency use authorization allowing the administration of a single 50 µg (0.25 mL) homologous booster dose to individuals 18 years of age or older, at least 5 months after completion of a primary series of this vaccine (i.e., as a homologous booster dose), and to authorize use of the vaccine as a single booster dose following completion of primary vaccination with another authorized or approved COVID-19 vaccine (i.e., as a heterologous booster dose) in individuals 18 years of age or older. The dosing interval for the heterologous booster dose is the same as that authorized for a booster dose of the vaccine used for primary vaccination..

Continuous, ongoing safety surveillance under the oversight of FDA and CDC will actively and passively monitor for risks of myocarditis and pericarditis and other known and unknown short and long term risks of the booster doses authorized.


Review Memorandum Addendum # 3

Date: January 6, 2022
To: The File
From: Peter Marks, MD, PhD (CBER/OD) Peter W. Marks -S
Applicant name: Janssen Biotech, Inc.
Application Number: EUA 27205
Product: Janssen COVID-19 Vaccine
Subject: Addendum # 3 to CBER's review memorandum dated October 20, 2021 entitled, "EUA amendment to support use of a Janssen COVID-19 Vaccine heterologous booster dose following primary vaccination with other authorized COVID-19 vaccines"

Digitally signed by Peter W. Marks -S
 DN: c=US, o=U.S. Government, ou=FDA,
 ou=FDA, ou=People, cn=Peter W. Marks -S,
 6.9.2.342.19200300.124.1.1.2009932714
 Date: 2022.01.06 16:05:24 -0500

This addendum documents the Agency's determination to amend the existing EUA for the Janssen COVID-19 Vaccine to include the use of the Janssen COVID-19 Vaccine as a heterologous booster dose at least five (5) months after completion of a primary vaccination series with the Moderna COVID-19 Vaccine in individuals 18 years of age and older.

I. Background

On October 20, 2021, FDA authorized for emergency use the administration of a single booster dose of Janssen COVID-19 Vaccine as a heterologous booster dose following completion of primary vaccination with another authorized or approved COVID-19 vaccine, where the eligible population(s) and dosing interval for the heterologous booster dose were the same as those authorized for a homologous booster dose of the vaccine used for primary vaccination.¹ The eligible population was subsequently amended on November 19, 2021. FDA authorized the use of the Janssen COVID-19 Vaccine as a heterologous booster dose in individuals 18 years of age or older, where the dosing interval for the heterologous booster dose is the same as that authorized for a booster dose of the vaccine used for primary vaccination. At the time, the dosing

¹ A single booster dose of the Moderna COVID-19 Vaccine and the Pfizer-BioNTech COVID-19 Vaccine was authorized for administration to individuals 65 years of age and older, individuals 18 through 64 years of age at high risk of severe COVID-19, and individuals 18 through 64 years of age with frequent institutional or occupational exposure to SARS-CoV-2.



interval for the Moderna COVID-19 Vaccine was six (6) months after completion of the primary vaccination series.²

Following the authorization, the first confirmed case of the SARS-CoV-2 variant Omicron (B.1.1.529) was identified in the United States. Since that time, the proportion of cases due to the Omicron variant is estimated to have increased to over 50% and is rising. This rapid increase in the proportion of cases attributable to the Omicron variant, relative to the previously highly prevalent SARS-CoV-2 variant Delta (B.1.617.2), is contemporaneous with a surge in COVID-19 cases in the United States. Laboratory data indicate that the Omicron variant is more resistant to neutralization by the antibodies generated with the currently available COVID-19 vaccines, and that a single additional vaccine dose may provide improved protection against the Omicron variant.

As explained in more detail in the review memorandum entitled "CBER assessment of a single booster dose of the Moderna COVID-19 Vaccine (0.25 mL) administered at 5 months," the Agency is amending the Moderna COVID-19 Vaccine EUA to authorize the use of a single booster dose of the Moderna Vaccine at least **five (5)** months after completion of a primary vaccination series with the Moderna COVID-19 Vaccine.³ As noted above, the dosing interval for the heterologous booster dose is the same as that authorized for a booster dose of the vaccine used for primary vaccination. Consequently, the dosing interval for the Janssen COVID-19 Vaccine heterologous booster dose following primary vaccination by the Moderna COVID-19 Vaccine is being amended from six (6) months to five (5) months.

II. Discussion

As noted in our prior review memorandum dated October 20, 2021, in considering the appropriate populations that would be eligible for a heterologous booster dose and the appropriate interval between primary vaccination and a heterologous booster dose, the need for a booster dose is determined by immunity elicited by the primary vaccination. Thus, the eligible population(s) and dosing interval for a Janssen COVID-19 Vaccine heterologous booster dose that would be supported by available data would be the same as those authorized for a homologous booster dose of the vaccine used for primary vaccination. Additionally, the NIH study that originally supported the use of heterologous booster doses, which was evaluated and presented at the October 15, 2021 Vaccines and Related Biologic Products Advisory Committee meeting and discussed in detail in our Oct. 20, 2021 memorandum, also supports the use of heterologous booster doses in individuals 18 years of age and older at least 5 months following primary vaccination under EUA. Specifically, in this study, the median booster interval was 19.3

² On January 3, 2021, FDA authorized the use of the Janssen COVID-19 Vaccine as a heterologous booster dose at least five (5) months after completion of a primary vaccination series with the Pfizer-BioNTech COVID-19 Vaccine in individuals 18 years of age and older.

³ CBER's review and analysis of the use of the homologous booster dose of the Moderna COVID-19 Vaccine is documented in a separate review memorandum: "CBER assessment of a single booster dose of the Moderna COVID-19 Vaccine (0.25 mL) administered at 5 months," dated December 30, 2021, and is incorporated here by reference.



weeks (range 12.6 – 26.0) for the 49 individuals who completed primary vaccination with the Moderna COVID-19 Vaccine and boosted with the Janssen COVID-19 Vaccine.

Therefore, based on the totality of the data, the Janssen COVID-19 Vaccine, when administered as a heterologous booster dose following completion of primary vaccination with another authorized or approved COVID-19 vaccine, may be effective in improving protection against serious outcomes of COVID-19 among individuals in whom immunity elicited by primary vaccination have waned. This includes the use of the Janssen COVID-19 Vaccine as a heterologous booster dose at least five (5) months after completion of a primary vaccination series with the Moderna COVID-19 Vaccine in individuals 18 years of age and older. Additionally, the known and potential benefits outweigh the known and potential risks for use of a heterologous booster dose of the Janssen COVID-19 Vaccine when administered to individuals 18 years of age and older who have completed primary vaccination with this vaccine or with another authorized or approved COVID-19 vaccine and where the dosing interval for the heterologous booster dose is the same as that authorized for a homologous booster dose of the vaccine used for primary vaccination, which now includes at least five (5) months for those individuals who have completed a primary vaccination series with the Moderna COVID-19 Vaccine.⁴

⁴ Another criterion for issuing an EUA under section 564 of the Federal Food, Drug, and Cosmetic Act is that there “is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating the disease or condition.” Although COMIRNATY (COVID-19 Vaccine, mRNA) is approved to prevent COVID-19 in individuals 16 years of age and older, there are no COVID-19 vaccines that are approved to provide homologous or heterologous booster doses.


Review Memorandum Addendum # 2

Date: January 6, 2022

To: The File

From: Peter Marks, MD, PhD (CBER/OD) Peter W. Marks -S

Applicant name: Pfizer, Inc., on behalf of Pfizer and BioNTech

Application Number: EUA 27034

Product: Pfizer-BioNTech COVID-19 Vaccine

Subject: Addendum # 2 to CBER's review memorandum dated October 20, 2021 entitled, "EUA amendment to support use of a Pfizer-BioNTech COVID-19 Vaccine heterologous booster dose following primary vaccination with other authorized COVID-19 vaccines"

Digitally signed by Peter W. Marks -S
 DN: c=US, o=U.S. Government, ou=FDA, ou=People, ou=Peter W. Marks -S,
 0.9.2342.1.1000.100.1.1=300312716,
 Date: 2022.01.06 16:06:47 -0500

This addendum documents the Agency's determination to amend the existing EUA for the Pfizer-BioNTech COVID-19 Vaccine to include the use of the Pfizer-BioNTech COVID-19 Vaccine¹ as a heterologous booster dose at least five (5) months after completion of a primary vaccination series with the Moderna COVID-19 Vaccine in individuals 18 years of age and older.

I. Background

On October 20, 2021, FDA authorized for emergency use the administration of a single booster dose of Pfizer-BioNTech COVID-19 Vaccine as a heterologous booster dose following completion of primary vaccination with another authorized or approved COVID-19 vaccine, where the eligible population(s) and dosing interval for the heterologous booster dose were the same as those authorized for a homologous booster dose of the vaccine used for primary vaccination.² The eligible population was subsequently amended on November 19, 2021. FDA authorized the use of the Pfizer-BioNTech COVID-19 Vaccine as a heterologous booster dose in individuals 18 years of age or older, where the dosing interval for the heterologous booster dose is the same as that authorized for a booster dose of the vaccine used for primary vaccination. At

¹ References to Pfizer-BioNTech COVID-19 Vaccine in this memo also apply to COMIRNATY (COVID-19 Vaccine, mRNA).

² A single booster dose of the Moderna COVID-19 Vaccine and the Pfizer-BioNTech COVID-19 Vaccine was authorized for administration to individuals 65 years of age and older, individuals 18 through 64 years of age at high risk of severe COVID-19, and individuals 18 through 64 years of age with frequent institutional or occupational exposure to SARS-CoV-2.



the time, the dosing interval for the Moderna COVID-19 Vaccine was six (6) months after completion of the primary vaccination series.

Following the authorization, the first confirmed case of the SARS-CoV-2 variant Omicron (B.1.1.529) was identified in the United States. Since that time, the proportion of cases due to the Omicron variant is estimated to have increased to over 50% and is rising. This rapid increase in the proportion of cases attributable to the Omicron variant, relative to the previously highly prevalent SARS-CoV-2 variant Delta (B.1.617.2), is contemporaneous with a surge in COVID-19 cases in the United States. Laboratory data indicate that the Omicron variant is more resistant to neutralization by the antibodies generated with the currently available COVID-19 vaccines, and that a single additional vaccine dose may provide improved protection against the Omicron variant.

As explained in more detail in the review memorandum entitled "CBER assessment of a single booster dose of the Moderna COVID-19 Vaccine (0.25 mL) administered at 5 months," the Agency is amending the Moderna COVID-19 Vaccine EUA to authorize the use of a single booster dose of the Moderna Vaccine at least **five (5) months** after completion of a primary vaccination series with the Moderna COVID-19 Vaccine.³ As noted above, the dosing interval for the heterologous booster dose is the same as that authorized for a booster dose of the vaccine used for primary vaccination. Consequently, the dosing interval for the Pfizer-BioNTech COVID-19 Vaccine heterologous booster dose following primary vaccination by the Moderna COVID-19 Vaccine is being amended from six (6) months to five (5) months.

II. Discussion

As noted in our prior review memorandum dated October 20, 2021, in considering the appropriate populations that would be eligible for a heterologous booster dose and the appropriate interval between primary vaccination and a heterologous booster dose, the need for a booster dose is determined by immunity elicited by the primary vaccination. Thus, the eligible population(s) and dosing interval for a Pfizer-BioNTech COVID-19 Vaccine heterologous booster dose that would be supported by available data would be the same as those authorized for a homologous booster dose of the vaccine used for primary vaccination. Additionally, the NIH study that originally supported the use of heterologous booster doses, which was evaluated and presented at the October 15, 2021 VRBPAC meeting and discussed in detail in our Oct. 20, 2021 memo, also supports the use of heterologous booster doses in individuals 18 years of age and older at least 5 months following primary vaccination under EUA. Specifically, in this study, the median booster interval was 22.9 weeks (range 12.6 – 28.7) for the 51 individuals who completed primary vaccination with the Moderna COVID-19 Vaccine and boosted with the Pfizer-BioNTech COVID-19 Vaccine.

³ CBER's review and analysis of the use of the homologous booster dose of the Moderna COVID-19 Vaccine is documented in a separate review memorandum: "CBER assessment of a single booster dose of the Moderna COVID-19 Vaccine (0.25 mL) administered at 5 months," dated January 6, 2022, and is incorporated here by reference.



Therefore, based on the totality of the data, the Pfizer-BioNTech COVID-19 Vaccine, when administered as a heterologous booster dose following completion of primary vaccination with another authorized or approved COVID-19 vaccine, may be effective in improving protection against serious outcomes of COVID-19 among individuals in whom immunity elicited by primary vaccination have waned. This includes the use of the Pfizer-BioNTech COVID-19 Vaccine as a heterologous booster dose at least five (5) months after completion of a primary vaccination series with the Moderna COVID-19 Vaccine in individuals 18 years of age and older. Additionally, the known and potential benefits outweigh the known and potential risks for use of a heterologous booster dose of the Pfizer-BioNTech COVID-19 Vaccine when administered to individuals 18 years of age and older who have completed primary vaccination with this vaccine or with another authorized or approved COVID-19 vaccine and where the dosing interval for the heterologous booster dose is the same as that authorized for a homologous booster dose of the vaccine used for primary vaccination, which now includes at least five (5) months for those individuals who have completed a primary vaccination series with the Moderna COVID-19 Vaccine.⁴

⁴ Another criterion for issuing an EUA under section 564 of the Federal Food, Drug, and Cosmetic Act is that there “is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating the disease or condition.” Although COMIRNATY (COVID-19 Vaccine, mRNA) is approved to prevent COVID-19 in individuals 16 years of age and older, there are no COVID-19 vaccines that are approved to provide homologous or heterologous booster doses.

From: Hussain, Sana [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5EE10CDD4E6148579481016D45303CAD-SANA.HUSSAI]
Sent: 8/23/2021 8:32:36 AM
To: Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]
Subject: FW: BLA Comirnaty - sign off on clinical review memo
Attachments: STN 125742-0 Approval letter_final.pdf; STN 125742-0_SBRA_Ramachandra Naik_8.23.2021_rsn.pdf; STN125742.0 Transmittal Memo.pdf

From: Marks, Peter <[REDACTED]>
Sent: Monday, August 23, 2021 8:31 AM
To: Sadove, Elizabeth <[REDACTED]> Courtney, Brooke <[REDACTED]>
Cc: Hussain, Sana <[REDACTED]> McNeill, Lorrie <[REDACTED]>
Subject: FW: BLA Comirnaty - sign off on clinical review memo

Dear Liz and Brooke,

Please see the attached. The approval letter has been signed. Please proceed with the LoA/EUA materials.

Best Regards,
Peter

From: Gruber, Marion <[REDACTED]>
Sent: Monday, August 23, 2021 8:29 AM
To: Malarkey, Mary <[REDACTED]> Marks, Peter <[REDACTED]>
Cc: Naik, Ramachandra <[REDACTED]> Smith, Michael (CBER) <[REDACTED]>
Dickerson, David <[REDACTED]> Gottschalk, Laura <[REDACTED]>
Subject: RE: BLA Comirnaty - sign off on clinical review memo

Dear Ram,
All three documents have been signed off and locked.
Marion

From: Malarkey, Mary <Mary.Mala[REDACTED]>
Sent: Monday, August 23, 2021 8:20 AM
To: Gruber, Marion <Marion.G[REDACTED]>
Cc: Naik, Ramachandra <Ra[REDACTED]> Smith, Michael (CBER) <[REDACTED]>
Dickerson, David <David[REDACTED]>
Subject: RE: BLA Comirnaty - sign off on clinical review memo

OK – I went ahead per instructions. Here they are unlocked

From: Gruber, Marion <[REDACTED]>
Sent: Monday, August 23, 2021 8:10 AM
To: Malarkey, Mary <[REDACTED]>
Cc: Naik, Ramachandra <[REDACTED]> Smith, Michael (CBER) <[REDACTED]>
Dickerson, David <[REDACTED]>
Subject: RE: BLA Comirnaty - sign off on clinical review memo

just talked to Peter, he asked to wait until 8:15 am, if clinical memo not signed by then, we start our sign off.

From: Malarkey, Mary <[REDACTED]>
Sent: Monday, August 23, 2021 8:06 AM
To: Gruber, Marion <[REDACTED]>
Subject: RE: BLA Comirnaty - sign off on clinical review memo

Ok – I'll hang

From: Gruber, Marion <[REDACTED]>
Sent: Monday, August 23, 2021 8:05 AM
To: Malarkey, Mary <Ma[REDACTED]>
Subject: RE: BLA Comirnaty - sign off on clinical review memo

Wait 10 more minutes so that we can be sure memo is signed. Peter is a bit behind too, I guess, he was supposed to call me at 8:00 am 😊

From: Malarkey, Mary <[REDACTED]>
Sent: Monday, August 23, 2021 8:04 AM
To: Gruber, Marion <[REDACTED]>
Subject: RE: BLA Comirnaty - sign off on clinical review memo

Should I go ahead?

From: Gruber, Marion <[REDACTED]>
Sent: Monday, August 23, 2021 7:57 AM
To: Fink, Doran <[REDACTED]> Marks, Peter <Peter[REDACTED]>
Cc: Malarkey, Mary <[REDACTED]> Fink, Ramachandra <[REDACTED]> Smith, Michael (CBER) <[REDACTED]> Dickerson, David <[REDACTED]>
Subject: RE: BLA Comirnaty - sign off on clinical review memo

Great!

From: Fink, Doran <[REDACTED]>
Sent: Monday, August 23, 2021 7:56 AM
To: Gruber, Marion <[REDACTED]> Marks, Peter <[REDACTED]>
Cc: Malarkey, Mary <[REDACTED]> Naik, Ramachandra <[REDACTED]> Smith, Michael (CBER) <[REDACTED]> Dickerson, David <[REDACTED]>
Subject: RE: BLA Comirnaty - sign off on clinical review memo

Update – just heard that the memo is ready to PDF and sign, so they are working on that now.

Thanks
Doran

Doran L. Fink, MD, PhD
Deputy Director – Clinical
Division of Vaccines and Related Products Applications
FDA/CBER, Office of Vaccines Research and Review
[REDACTED]

From: Gruber, Marion <[REDACTED]>

Sent: Monday, August 23, 2021 7:54 AM

To: Marks, Peter <[REDACTED]>

Cc: Malarkey, Mary <[REDACTED]> Naik, Ramachandra <[REDACTED]> Smith, Michael (CBER) <[REDACTED]>; Dickerson, David <[REDACTED]>; Fink, Doran <[REDACTED]>

Subject: BLA Comirnaty - sign off on clinical review memo

Dear Peter,

The clinical review memo is final and the editors finished cleaning it up overnight. However, the clinical team is working currently through some technical issues on SharePoint, they are trying to get the memo finalized and signed within the hour. Thus, these are solely IT issues that prevent us from finalizing and signing the memo. I suggest to go forward with signing off on the approval. The clinical review memo will be signed off and approved once all issues are solved.

Marion

Marion F. Gruber, Ph.D
Director

Office of Vaccines Research & Review
Center for Biologics Evaluation & Research
Food & Drug Administration, DHHS

Tel.: [REDACTED]
Email: [REDACTED]



Produced to Homeland Security and Government Affairs Permanent Subcommittee on Investigations Pursuant to Oversight Request
Do Not Disclose Without Permission from U.S. Department of Health and Human Services

[REDACTED]
[REDACTED]
[REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]

PSICOVID_00005476

FDA-CVD-TIERNEYJ-00256198-3

From: Marks, Peter [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DFBB2B5BD38445CB9C9ADCA3F72DF53A-MARKSP]
Sent: 8/19/2021 9:27:31 AM
To: Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]
CC: Hussain, Sana [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5ee10cdd4e6148579481016d45303cad-Sana.Hussai]
Subject: FW: PI
Attachments: STN 125742.0.58_Revised PI_CBER Edits_08.18.2021.docx

Dear Julie,

This is starting to look like a real product. Please let me know if you have any questions.

Best Regards,
Peter

From: Naik, Ramachandra <[REDACTED]>
Sent: Thursday, August 19, 2021 9:03 AM
To: Marks, Peter <[REDACTED]>
Subject: RE: PI

Dear Dr. Marks,

Please see the attached with 3 comments, sent to Pfizer yesterday. It's almost there, hoping to finalize today if Pfizer agrees to our edits.

Regards,
Ram

From: Marks, Peter <[REDACTED]>
Sent: Thursday, August 19, 2021 8:43 AM
To: Naik, Ramachandra <[REDACTED]>
Subject: PI

Dear Ram,

Could you send me a Word document of the latest package insert in progress – it's fine with all of the edits? Thanks so much.

Best Regards,
Peter

Our STN: BL 125742/0

BLA APPROVAL

BioNTech Manufacturing GmbH
Attention: Amit Patel
Pfizer Inc.
235 East 42nd Street
New York, NY 10017

August 23, 2021

Dear Mr. Patel:

Please refer to your Biologics License Application (BLA) submitted and received on May 18, 2021, under section 351(a) of the Public Health Service Act (PHS Act) for COVID-19 Vaccine, mRNA.

LICENSING

We are issuing Department of Health and Human Services U.S. License No. 2229 to BioNTech Manufacturing GmbH, Mainz, Germany under the provisions of section 351(a) of the PHS Act controlling the manufacture and sale of biological products. The license authorizes you to introduce or deliver for introduction into interstate commerce, those products for which your company has demonstrated compliance with establishment and product standards.

Under this license, you are authorized to manufacture the product, COVID-19 Vaccine, mRNA, which is indicated for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 16 years of age and older.

The review of this product was associated with the following National Clinical Trial (NCT) numbers: NCT04368728 and NCT04380701.

MANUFACTURING LOCATIONS

Under this license, you are approved to manufacture COVID-19 Vaccine, mRNA drug substance at Wyeth BioPharma Division of Wyeth Pharmaceuticals LLC, 1 Burtt Road, Andover, Massachusetts. The final formulated product will be manufactured, filled, labeled and packaged at Pfizer Manufacturing Belgium NV, Rijksweg 12, Puurs, Belgium and at Pharmacia & Upjohn Company LLC, 7000 Portage Road, Kalamazoo, Michigan. The diluent, 0.9% Sodium Chloride Injection, USP, will be manufactured at Hospira, Inc., (b) (4) and at Fresenius Kabi USA, LLC, (b) (4).

You may label your product with the proprietary name, COMIRNATY, and market it in 2.0 mL glass vials, in packages of 25 and 195 vials.

We did not refer your application to the Vaccines and Related Biological Products Advisory Committee because our review of information submitted in your BLA, including the clinical study design and trial results, did not raise concerns or controversial issues that would have benefited from an advisory committee discussion.

DATING PERIOD

The dating period for COVID-19 Vaccine, mRNA shall be 9 months from the date of manufacture when stored between -90°C to -60°C (-130°F to -76°F). The date of manufacture shall be no later than the date of final sterile filtration of the formulated drug product (at Pharmacia & Upjohn Company LLC in Kalamazoo, Michigan, the date of manufacture is defined as the date of sterile filtration for the final drug product; at Pfizer Manufacturing Belgium NV in Puurs, Belgium, it is defined as the date of the (b) (4)

Following the final sterile filtration, (b) (4), no reprocessing/reworking is allowed without prior approval from the Agency. The dating period for your drug substance shall be (b) (4) when stored at (b) (4). We have approved the stability protocols in your license application for the purpose of extending the expiration dating period of your drug substance and drug product under 21 CFR 601.12.

FDA LOT RELEASE

Please submit final container samples of the product in final containers together with protocols showing results of all applicable tests. You may not distribute any lots of product until you receive a notification of release from the Director, Center for Biologics Evaluation and Research (CBER).

BIOLOGICAL PRODUCT DEVIATIONS

You must submit reports of biological product deviations under 21 CFR 600.14. You should identify and investigate all manufacturing deviations promptly, including those associated with processing, testing, packaging, labeling, storage, holding and distribution. If the deviation involves a distributed product, may affect the safety, purity, or potency of the product, and meets the other criteria in the regulation, you must submit a report on Form FDA 3486 to the Director, Office of Compliance and Biologics Quality, electronically through the eBPDR web application or at the address below. Links for the instructions on completing the electronic form (eBPDR) may be found on CBER's web site at <https://www.fda.gov/vaccines-blood-biologics/report-problem-center-biologics-evaluation-research/biological-product-deviations>:

Food and Drug Administration
Center for Biologics Evaluation and Research
Document Control Center

10903 New Hampshire Ave.
WO71-G112
Silver Spring, MD 20993-0002

MANUFACTURING CHANGES

You must submit information to your BLA for our review and written approval under 21 CFR 601.12 for any changes in, including but not limited to, the manufacturing, testing, packaging or labeling of COVID-19 Vaccine, mRNA, or in the manufacturing facilities.

LABELING

We hereby approve the draft content of labeling including Package Insert, submitted under amendment 74, dated August 21, 2021, and the draft carton and container labels submitted under amendment 63, dated August 19, 2021.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, please submit the final content of labeling (21 CFR 601.14) in Structured Product Labeling (SPL) format via the FDA automated drug registration and listing system, (eLIST) as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>. Content of labeling must be identical to the Package Insert submitted on August 21, 2021. Information on submitting SPL files using eLIST may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As* at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>.

The SPL will be accessible via publicly available labeling repositories.

CARTON AND CONTAINER LABELS

Please electronically submit final printed carton and container labels identical to the carton and container labels submitted on August 19, 2021, according to the guidance for industry *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications* at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/providing-regulatory-submissions-electronic-format-certain-human-pharmaceutical-product-applications>.

All final labeling should be submitted as Product Correspondence to this BLA STN BL 125742 at the time of use and include implementation information on Form FDA 356h.

ADVERTISING AND PROMOTIONAL LABELING

You may submit two draft copies of the proposed introductory advertising and promotional labeling with Form FDA 2253 to the Advertising and Promotional Labeling Branch at the following address:

Food and Drug Administration
Center for Biologics Evaluation and Research
Document Control Center
10903 New Hampshire Ave.
WO71-G112
Silver Spring, MD 20993-0002

You must submit copies of your final advertising and promotional labeling at the time of initial dissemination or publication, accompanied by Form FDA 2253 (21 CFR 601.12(f)(4)).

All promotional claims must be consistent with and not contrary to approved labeling. You should not make a comparative promotional claim or claim of superiority over other products unless you have substantial evidence or substantial clinical experience to support such claims (21 CFR 202.1(e)(6)).

ADVERSE EVENT REPORTING

You must submit adverse experience reports in accordance with the adverse experience reporting requirements for licensed biological products (21 CFR 600.80), and you must submit distribution reports at monthly intervals as described in 21 CFR 600.81. For information on adverse experience reporting, please refer to the guidance for industry *Providing Submissions in Electronic Format—Postmarketing Safety Reports for Vaccines* at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/providing-submissions-electronic-format-postmarketing-safety-reports-vaccines>. For information on distribution reporting, please refer to the guidance for industry *Electronic Submission of Lot Distribution Reports* at <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Post-MarketActivities/LotReleases/ucm061966.htm>.

PEDIATRIC REQUIREMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We are deferring submission of your pediatric studies for ages younger than 16 years for this application because this product is ready for approval for use in individuals 16 years of age and older, and the pediatric studies for younger ages have not been completed.

Your deferred pediatric studies required under section 505B(a) of the Federal Food, Drug, and Cosmetic Act (FDCA) are required postmarketing studies. The status of these postmarketing studies must be reported according to 21 CFR 601.28 and section 505B(a)(4)(C) of the FDCA. In addition, section 506B of the FDCA and 21 CFR 601.70 require you to report annually on the status of any postmarketing commitments or required studies or clinical trials.

Label your annual report as an “**Annual Status Report of Postmarketing Study Requirement/Commitments**” and submit it to the FDA each year within 60 calendar days of the anniversary date of this letter until all Requirements and Commitments subject to the reporting requirements under section 506B of the FDCA are released or fulfilled. These required studies are listed below:

1. Deferred pediatric Study C4591001 to evaluate the safety and effectiveness of COMIRNATY in children 12 years through 15 years of age.

Final Protocol Submission: October 7, 2020

Study Completion: May 31, 2023

Final Report Submission: October 31, 2023

2. Deferred pediatric Study C459100 to evaluate the safety and effectiveness of COMIRNATY in infants and children 6 months to <12 years of age.

Final Protocol Submission: February 8, 2021

Study Completion: November 30, 2023

Final Report Submission: May 31, 2024

3. Deferred pediatric Study C4591023 to evaluate the safety and effectiveness of COMIRNATY in infants <6 months of age.

Final Protocol Submission: January 31, 2022

Study Completion: July 31, 2024

Final Report Submission: October 31, 2024

Submit the protocols to your IND 19736, with a cross-reference letter to this BLA STN BL 125742 explaining that these protocols were submitted to the IND. Please refer to the PMR sequential number for each study/clinical trial and the submission number as shown in this letter.

Submit final study reports to this BLA STN BL 125742. In order for your PREA PMRs to be considered fulfilled, you must submit and receive approval of an efficacy or a labeling

supplement. For administrative purposes, all submissions related to these required pediatric postmarketing studies must be clearly designated as:

- **Required Pediatric Assessment(s)**

We note that you have fulfilled the pediatric study requirement for ages 16 through 17 years for this application.

POSTMARKETING REQUIREMENTS UNDER SECTION 505(o)

Section 505(o) of the Federal Food, Drug, and Cosmetic Act (FDCA) authorizes FDA to require holders of approved drug and biological product applications to conduct postmarketing studies and clinical trials for certain purposes, if FDA make certain findings required by the statute (section 505(o)(3)(A), 21 U.S.C. 355(o)(3)(A)).

We have determined that an analysis of spontaneous postmarket adverse events reported under section 505(k)(1) of the FDCA will not be sufficient to assess known serious risks of myocarditis and pericarditis and identify an unexpected serious risk of subclinical myocarditis.

Furthermore, the pharmacovigilance system that FDA is required to maintain under section 505(k)(3) of the FDCA is not sufficient to assess these serious risks.

Therefore, based on appropriate scientific data, we have determined that you are required to conduct the following studies:

4. Study C4591009, entitled “A Non-Interventional Post-Approval Safety Study of the Pfizer-BioNTech COVID-19 mRNA Vaccine in the United States,” to evaluate the occurrence of myocarditis and pericarditis following administration of COMIRNATY.

We acknowledge the timetable you submitted on August 21, 2021, which states that you will conduct this study according to the following schedule:

Final Protocol Submission: August 31, 2021

Monitoring Report Submission: October 31, 2022

Interim Report Submission: October 31, 2023

Study Completion: June 30, 2025

Final Report Submission: October 31, 2025

5. Study C4591021, entitled “Post Conditional Approval Active Surveillance Study Among Individuals in Europe Receiving the Pfizer-BioNTech Coronavirus

Disease 2019 (COVID-19) Vaccine,” to evaluate the occurrence of myocarditis and pericarditis following administration of COMIRNATY.

We acknowledge the timetable you submitted on August 21, 2021, which states that you will conduct this study according to the following schedule:

Final Protocol Submission: August 11, 2021

Progress Report Submission: September 30, 2021

Interim Report 1 Submission: March 31, 2022

Interim Report 2 Submission: September 30, 2022

Interim Report 3 Submission: March 31, 2023

Interim Report 4 Submission: September 30, 2023

Interim Report 5 Submission: March 31, 2024

Study Completion: March 31, 2024

Final Report Submission: September 30, 2024

6. Study C4591021 substudy to describe the natural history of myocarditis and pericarditis following administration of COMIRNATY.

We acknowledge the timetable you submitted on August 21, 2021, which states that you will conduct this study according to the following schedule:

Final Protocol Submission: January 31, 2022

Study Completion: March 31, 2024

Final Report Submission: September 30, 2024

7. Study C4591036, a prospective cohort study with at least 5 years of follow-up for potential long-term sequelae of myocarditis after vaccination (in collaboration with Pediatric Heart Network).

We acknowledge the timetable you submitted on August 21, 2021, which states that you will conduct this study according to the following schedule:

Final Protocol Submission: November 30, 2021

Study Completion: December 31, 2026

Final Report Submission: May 31, 2027

8. Study C4591007 substudy to prospectively assess the incidence of subclinical myocarditis following administration of the second dose of COMIRNATY in a subset of participants 5 through 15 years of age.

We acknowledge the timetable you submitted on August 21, 2021, which states that you will conduct this assessment according to the following schedule:

Final Protocol Submission: September 30, 2021

Study Completion: November 30, 2023

Final Report Submission: May 31, 2024

9. Study C4591031 substudy to prospectively assess the incidence of subclinical myocarditis following administration of a third dose of COMIRNATY in a subset of participants 16 to 30 years of age.

We acknowledge the timetable you submitted on August 21, 2021, which states that you will conduct this study according to the following schedule:

Final Protocol Submission: November 30, 2021

Study Completion: June 30, 2022

Final Report Submission: December 31, 2022

Please submit the protocols to IND 19736, with a cross-reference letter to this BLA STN BL 125742 explaining that these protocols were submitted to the IND. Please refer to the PMR sequential number for each study/clinical trial and the submission number as shown in this letter.

Please submit final study reports to the BLA. If the information in the final study report supports a change in the label, the final study report must be submitted as a supplement to this BLA STN BL 125742. For administrative purposes, all submissions related to these postmarketing studies required under section 505(o) must be submitted to this BLA and be clearly designated as:

- **Required Postmarketing Correspondence under Section 505(o)**
- **Required Postmarketing Final Report under Section 505(o)**
- **Supplement contains Required Postmarketing Final Report under Section 505(o)**

Section 505(o)(3)(E)(ii) of the FDCA requires you to report periodically on the status of any study or clinical trial required under this section. This section also requires you to periodically report to FDA on the status of any study or clinical trial otherwise

undertaken to investigate a safety issue. In addition, section 506B of the FDCA and 21 CFR 601.70 require you to report annually on the status of any postmarketing commitments or required studies or clinical trials.

You must describe the status in an annual report on postmarketing studies for this product. Label your annual report as an **Annual Status Report of Postmarketing Requirements/Commitments** and submit it to the FDA each year within 60 calendar days of the anniversary date of this letter until all Requirements and Commitment, subject to the reporting requirements of section 506B of the FDCA are fulfilled or released. The status report for each study should include:

- the sequential number for each study as shown in this letter;
- information to identify and describe the postmarketing requirement;
- the original milestone schedule for the requirement;
- the revised milestone schedule for the requirement, if applicable;
- the current status of the requirement (i.e., pending, ongoing, delayed, terminated, or submitted); and,
- an explanation of the status for the study or clinical trial. The explanation should include how the study is progressing in reference to the original projected schedule, including, the patient accrual rate (i.e., number enrolled to date and the total planned enrollment).

As described in 21 CFR 601.70(e), we may publicly disclose information regarding these postmarketing studies on our website at <http://www.fda.gov/Drugs/Guidance/ComplianceRegulatoryInformation/PostmarketingPhaseIVCommitments/default.htm>.

We will consider the submission of your annual report under section 506B of the FDCA and 21 CFR 601.70 to satisfy the periodic reporting requirement under section 505(o)(3)(E)(ii) provided that you include the elements listed in section 505(o) and 21 CFR 601.70. We remind you that to comply with section 505(o), your annual report must also include a report on the status of any study or clinical trial otherwise undertaken to investigate a safety issue. Failure to periodically report on the status of studies or clinical trials required under section 505(o) may be a violation of FDCA section 505(o)(3)(E)(ii) and could result in regulatory action.

POSTMARKETING COMMITMENTS SUBJECT TO REPORTING REQUIREMENTS UNDER SECTION 506B

We acknowledge your written commitments as described in your letter of August 21, 2021 as outlined below:

10. Study C4591022, entitled “Pfizer-BioNTech COVID-19 Vaccine Exposure during Pregnancy: A Non-Interventional Post-Approval Safety Study of Pregnancy and Infant Outcomes in the Organization of Teratology Information Specialists (OTIS)/MotherToBaby Pregnancy Registry.”

Final Protocol Submission: July 1, 2021

Study Completion: June 30, 2025

Final Report Submission: December 31, 2025

11. Study C4591007 substudy to evaluate the immunogenicity and safety of lower dose levels of COMIRNATY in individuals 12 through <30 years of age.

Final Protocol Submission: September 30, 2021

Study Completion: November 30, 2023

Final Report Submission: May 31, 2024

12. Study C4591012, entitled “Post-emergency Use Authorization, Active Safety Surveillance Study Among Individuals in the Veteran’s Affairs Health System Receiving Pfizer-BioNTech Coronavirus Disease 2019 (COVID-19) Vaccine.”

Final Protocol Submission: January 29, 2021

Study Completion: June 30, 2023

Final Report Submission: December 31, 2023

13. Study C4591014, entitled “Pfizer-BioNTech COVID-19 BNT162b2 Vaccine Effectiveness Study - Kaiser Permanente Southern California.”

Final Protocol Submission: March 22, 2021

Study Completion: December 31, 2022

Final Report Submission: June 30, 2023

Please submit clinical protocols to your IND 19736, and a cross-reference letter to this BLA STN BL 1257, explaining that these protocols were submitted to the IND. Please refer to the PMC sequential number for each study/clinical trial and the submission number as shown in this letter.

If the information in the final study report supports a change in the label, the final study report must be submitted as a supplement. Please use the following designators to prominently label all submissions, including supplements, relating to these postmarketing study commitments as appropriate:

- **Postmarketing Commitment – Correspondence Study Update**
- **Postmarketing Commitment – Final Study Report**
- **Supplement contains Postmarketing Commitment – Final Study Report**

For each postmarketing study subject to the reporting requirements of 21 CFR 601.70, you must describe the status in an annual report on postmarketing studies for this product. Label your annual report as an **Annual Status Report of Postmarketing Requirements/Commitments** and submit it to the FDA each year within 60 calendar days of the anniversary date of this letter until all Requirements and Commitments subject to the reporting requirements of section 506B of the FDCA are fulfilled or released. The status report for each study should include:

- the sequential number for each study as shown in this letter;
- information to identify and describe the postmarketing commitment;
- the original schedule for the commitment;
- the status of the commitment (i.e., pending, ongoing, delayed, terminated, or submitted); and,
- an explanation of the status including, for clinical studies, the patient accrual rate (i.e., number enrolled to date and the total planned enrollment).

As described in 21 CFR 601.70(e), we may publicly disclose information regarding these postmarketing studies on our website at <http://www.fda.gov/Drugs/Guidance/ComplianceRegulatoryInformation/Post-marketingPhaseICommitments/default.htm>.

POST APPROVAL FEEDBACK MEETING

New biological products qualify for a post approval feedback meeting. Such meetings are used to discuss the quality of the application and to evaluate the communication process during drug development and marketing application review. The purpose is to learn from successful aspects of the review process and to identify areas that could benefit from improvement. If you would like to have such a meeting with us, please contact the Regulatory Project Manager for this application.

Sincerely,

Mary A. Malarkey
Director
Office of Compliance
and Biologics Quality
Center for Biologics
Evaluation and Research

Marion F. Gruber, PhD
Director
Office of Vaccines
Research and Review
Center for Biologics
Evaluation and Research

From: Marks, Peter [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DFBB2B5BD38445CB9C9ADCA3F72DF53A-MARKSP]
Sent: 9/7/2021 5:22:08 PM
To: Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]; Collins, Francis S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5257472fae794b85b15c27eb54598d70-HHS-collins]; Mascola, John R (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=63aa50129c1f4d39bc0a31b3851a34c5-HHS-jmascol]; Johnson, Robert (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9c7eb3a419464ea2917f9d1e3f6e57a4-HHS-Robert.]; O'Connell, Dawn (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7871c174f90c49b3952e7639829f176d-HHS-Dawn.Oc]; Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]
CC: Walinsky, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=97a2ad6b3c4549a78542fce1a086f7ea-Sarah.Walin]
Subject: RE: Moderna Dosage for Third Dose (50 v 100)
Attachments: Additional Doses 090721.pptx

Dear All,

Thanks so much for a really great meeting. Please see the slideset used attached.

Best Regards,
Peter

Additional Dose Planning

September 7, 2021

Produced to Homeland Security and Government Affairs Permanent Subcommittee on Investigations Pursuant to Oversight Request
Do Not Disclose Without Permission from U.S. Department of Health and Human Services



Assumptions

- Data (Israel, Kaiser) indicate that those ≥ 65 years vaccinated > 6 months ago need a booster
 - Pfizer, Moderna, Janssen
- Data suggest those < 65 vaccinated > 6 months ago may need a booster now or shortly
 - Israeli data using Pfizer vaccine available Sept 10
 - Currently assessing other sources of data

Produced to Homeland Security and Government Affairs Permanent Subcommittee on Investigations Pursuant to Oversight Request
Do Not Disclose Without Permission from U.S. Department of Health and Human Services



Question for Today

- Assuming that additional vaccine dose will be needed across the population in the coming months, for Moderna what is the right dose?
 - 50 mcg
 - 100 mcg
 - 50 mcg for age < X, 100 mcg for age $\geq$ X

Produced to Homeland Security and Government Affairs Permanent Subcommittee on Investigations Pursuant to Oversight Request
Do Not Disclose Without Permission from U.S. Department of Health and Human Services

3rd dose of Moderna WT vaccine at either 50ug or 100ug yields PsVNA titers higher than post-2nd dose peak

Cohort	3 rd dose	Time between 2 nd and 3 rd dose (months)	# subjects for immuno readout	GMT on day of 3 rd dose	Immuno timepoint after 3 rd dose	GMT after 3 rd dose (A)	Comparator cohort	Peak immuno timepoint	Primary Peak GMT (B)	Post 3 rd dose GMT over Primary peak (A/B)
DMID 21-0012	100 ug	2.8 – 4.6 months	N = 50	366	Day 15	3727	Ph3 (P301)	Day 57	1081	3.4
Moderna P201 – Part B	50 ug	> 5.5 months*	N = 350	126	Day 29	1893	Ph3 (P301)	Day 57	1081	1.5

Recap of recent readouts:

- 3rd dose with 50 ug boosts pseudo-neut titers to ~1.8X over primary series peak (Moderna P201-B)
- 3rd dose with 100 ug boosts pseudo-neut titers to ~3.4x over primary series peak (DMID 21-0012)

For reference: Pfizer
Day 29 after 3rd dose
3.3x Day 29 after 2nd dose

However, need to consider potential confounders:

- Moderna P201-B 3rd administered > 6 months post second dose, while interval for DMID study was ~3-5 months
- 50 ug 3rd dose immunogenicity readout is for Day 29, whereas that for 100 ug is for Day 15. We have seen previously that there is a small but noticeable drop in titers between Days 15 and 29 (see next page for details)

Note: Pseudo-virus neutralization assay results come from D Montefiori lab (Duke)

* Less than 6 months from 2nd dose

FOR OFFICIAL USE ONLY - DO NOT DISTRIBUTE

Backup: A subset of the data shows a minor drop in GMT between 15 and 29 days post 3rd dose

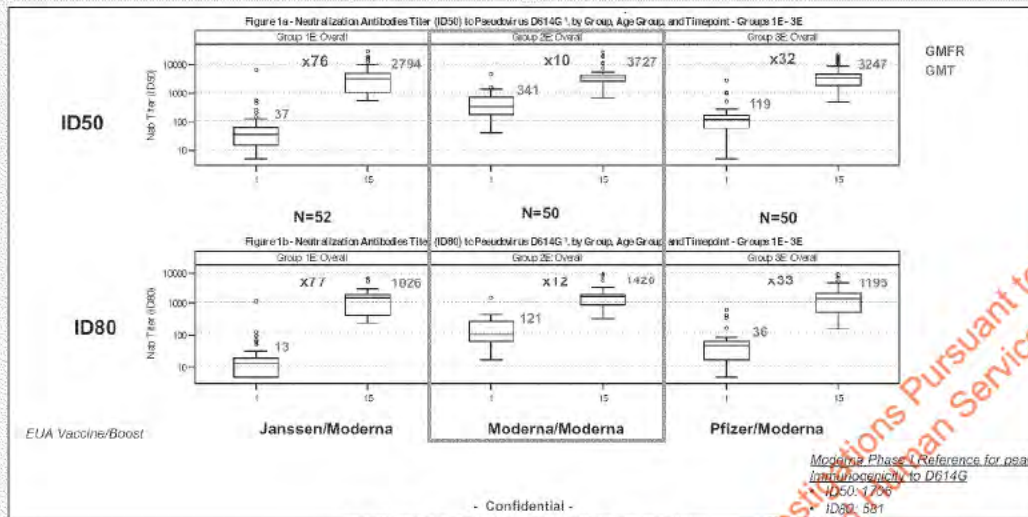
Cohort	3 rd dose	Time between 2 nd and 3 rd dose (months)	# subjects for immuno readout	GMT on day of 3 rd dose	Immuno timepoint after 3 rd dose	GMT after 3 rd dose (A)	Comparator cohort	Peak immuno timepoint	Primary Peak GMT (B)	Post 3 rd dose GMT over Primary peak (A/B)
DMID 21-0012	100 ug	2.8 – 4.6 months	N = 50	366	Day 15	3727	Ph3 (P301)	Day 57	1081	3.4
Moderna P201 – Part B (full set)	50 ug	> 5.5 months	N = 350	126	Day 29	1893	Ph3 (P301)	Day 57	1081	1.8
Moderna P201 – Part B (subset)	50 ug	> 5.5 months*	N=30	215	Day 15	2321	Ph3 (P301)	Day 57	1081	2.1
	50 ug	> 5.5 months*	N=30	215	Day 29	1793	Ph3 (P301)	Day 57	1081	1.7

Timepoint comparison (Day 15 vs Day 29)

- Highlighted data above are from subset of 30 subjects from Moderna P201 – Part B whose samples were tested on both Days 15 and Day 29 after 3rd dose
- There is a small but noticeable drop between Day 15 and Day 29 after 3rd dose (from 2321 to 1793 in above table)

FOR OFFICIAL USE ONLY - DO NOT DISTRIBUTE

DMID 21-0012: Pseudovirus neutralization antibody titers through D15 post 100ug WT boost (1/2)





Pros and Cons

	Pros	Cons
50 mcg	More doses available Possible lower myocarditis risk	Potential operational complexity Need to optimally use doses from vial Possible issue with heterologous boost
100 mcg	Possibility of more durable effect Operationally simpler overall	Fewer doses available Possible higher myocarditis risk

www.fda.gov

7

Produced to Homeland Security and Government Affairs Permanent Subcommittee on Investigations Pursuant to Oversight Request
Do Not Disclose Without Permission from U.S. Department of Health and Human Services



U.S. FOOD & DRUG
ADMINISTRATION

Produced to Homeland Security and Government Affairs Permanent Subcommittee on Investigations Pursuant to Oversight Request
Do Not Disclose Without Permission from U.S. Department of Health and Human Services

RE: Media inquiry from Zach Stieber with The Epoch Time on Spikevax

From: "Pfaeffle, Veronika" <[REDACTED]>
To: "Richards, Paul" <[REDACTED]>
Cc: "Frantz-Bohn, Susan" <[REDACTED]> "Hunt, Alison" <[REDACTED]>
"Capobianco, Abigail" <[REDACTED]> "Bartell, Diane" <[REDACTED]>
"McNeill, Lorrie" <[REDACTED]>
Date: Thu, 03 Feb 2022 16:28:57 -0500

Thank you, Paul.

Veronika Pfaeffle
Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel: [REDACTED]
[REDACTED]



From: Richards, Paul <[REDACTED]>
Sent: Thursday, February 3, 2022 4:10 PM
To: Pfaeffle, Veronika <[REDACTED]>
Cc: Frantz-Bohn, Susan <[REDACTED]> "Hunt, Alison" <[REDACTED]> Capobianco, Abigail
<[REDACTED]> Bartell, Diane <[REDACTED]> McNeill, Lorrie
<[REDACTED]>
Subject: RE: Media inquiry from Zach Stieber with The Epoch Time on Spikevax

Hi Veronika,

We recommend that OMA provide the following in response to this request:

The meta-analysis used data from four large private health insurance claims systems who are part of the BEST system. More information on BEST is available [here](#). The results we used are included in the Benefit-Risk Assessment Review Memorandum, which will be posted [here](#) - along with the rest of the review documents (i.e. action package) related to Spikevax. The action package will be posted following our disclosure review according to Section 916 of the Food and Drug Administration Amendments Act (FDAAA) of 2007.

Note: If the reporter requests clarification about what the timing of availability you can direct him to CBER's SOPP ([8401.7: Action Package for Posting](#)).

Best,

Paul

From: Pfaeffle, Veronika <[REDACTED]>
Sent: Tuesday, February 01, 2022 4:28 PM
To: Richards, Paul <[REDACTED]>
Cc: Frantz-Bohn, Susan <[REDACTED]> "Hunt, Alison" <[REDACTED]> Capobianco, Abigail <[REDACTED]> Bartell, Diane <[REDACTED]> McNeill, Lorrie
<[REDACTED]>
Subject: RE: Media inquiry from Zach Stieber with The Epoch Time on Spikevax

PSICOVID_00005517

Hi Alison –

Apologies for the delay in getting back to you on this. Our response is below. If you have questions, please let Susan or me know.

Thanks –

Lorrie

In contrast to the assertions in the media and social media, communicating the benefits and risks of medical products is a responsibility that FDA takes very seriously.

FDA cannot comment on or respond to questions about an individual's medical information. Additionally, FDA is not able to provide medical advice or guidance and does not have a role in active clinical research about treatment of adverse events.

You asked about FDA's review of reported adverse events for autoimmune disorders. To date, the systems in place to monitor the safety of the COVID-19 vaccines authorized or approved for use in the U.S. have identified several health problems potentially associated with vaccination but not autoimmune disorders. These include [Guillain Barré syndrome](#) (a neurological disorder in which the body's immune system damages nerve cells, causing muscle weakness and sometimes paralysis) and [thrombosis with thrombocytopenia](#) (TTS) following the Janssen COVID-19 vaccine, and [myocarditis and pericarditis](#) following the Pfizer-BioNTech and Moderna COVID-19 vaccines. The chance of having these events occur is very low. Additionally, anaphylaxis has been reported.

The Fact Sheets for Healthcare Providers Administering Vaccine (Vaccination Providers) for each of the [COVID-19 vaccines](#) available for use in the U.S. have been revised to include information from post-authorization safety surveillance discussed above, including information in the Warning section pertaining to risks that have been identified. The Fact Sheets for Recipients and Caregivers have also been revised to include information about safety obtained from post-authorization safety surveillance.

The physicians, and epidemiologists from FDA and CDC continuously screen and analyze VAERS data for COVID-19 vaccines to identify potential signals that would indicate the need for further study. This includes scientific consultation with neurologists and immunologists and our colleagues at the National Institutes of Health (NIH).

The analyses conducted by FDA include review of individual reports, aggregate analysis of VAERS data, and generating case series when indicated for possible safety concerns. In the course of these reviews, FDA has found that many reports do not represent side effects due to the vaccine. This may be because the diagnosis is not correct, medical records reveal the symptoms began prior to vaccination, or the patient has underlying medical conditions that explain the adverse event.

Decisions on whether there is some basis to believe there is a causal relationship are a matter of medical and scientific judgment and are based on factors such as: the frequency of reporting, biological plausibility, the timing of the event relative to the time of vaccination, and whether the adverse event is known to be caused by related vaccines. It is important to note that signals of rare adverse events can be detected, such as was the case in April 2021, when FDA and CDC physicians initially identified six serious adverse event reports (including 3 deaths) of thrombosis with thrombocytopenia syndrome (TTS) out of 6.8 million individuals that had been vaccinated with the Janssen COVID-19 vaccine.

FDA and CDC will continue to carefully monitor reports of all adverse event reports and [update](#) the public as more information becomes available.

Additional information of vaccine safety monitoring can be found on the web at the following links:

- [COVID-19 Vaccine Safety Surveillance | FDA](#)
- [Ensuring COVID-19 Vaccine Safety in the US | CDC](#)

From: Hunt, Alison <[Alison.Hunt@FDA.gov](#)>
Sent: Friday, January 28, 2022 3:23 PM
To: McNeill, Lorrie <[Lorrie.McNeill@FDA.gov](#)>
Cc: Capobianco, Abigail <[Abigail.Capobianco@FDA.gov](#)> Pfaeffle, Veronika <[Veronika.Pfaeffle@FDA.gov](#)>
Subject: RE: Media inquiry: Epoch Times, COVID-19 Vaccine Injury Research

Totally understood.

Alison Hunt, MPH
Press Officer

PSICOVID_00005518

Bohn, Susan <[REDACTED]>
Subject: RE: Media inquiry: Epoch Times, COVID-19 Vaccine Injury Research

Hi Alison –

Apologies for the delay in getting back to you on this. Our response is below. If you have questions, please let Susan or me know.

Thanks –

Lorrie

In contrast to the assertions in the media and social media, communicating the benefits and risks of medical products is a responsibility that FDA takes very seriously.

FDA cannot comment on or respond to questions about an individual's medical information. Additionally, FDA is not able to provide medical advice or guidance and does not have a role in active clinical research about treatment of adverse events.

You asked about FDA's review of reported adverse events for autoimmune disorders. To date, the systems in place to monitor the safety of the COVID-19 vaccines authorized or approved for use in the U.S. have identified several health problems potentially associated with vaccination but not autoimmune disorders. These include [Guillain Barré syndrome](#) (a neurological disorder in which the body's immune system damages nerve cells, causing muscle weakness and sometimes paralysis) and [thrombosis with thrombocytopenia](#) (TTS) following the Janssen COVID-19 vaccine, and [myocarditis and pericarditis](#) following the Pfizer-BioNTech and Moderna COVID-19 vaccines. The chance of having these events occur is very low. Additionally, anaphylaxis has been reported.

The Fact Sheets for Healthcare Providers Administering Vaccine (Vaccination Providers) for each of the [COVID-19 vaccines](#) available for use in the U.S. have been revised to include information from post-authorization safety surveillance discussed above, including information in the Warning section pertaining to risks that have been identified. The Fact Sheets for Recipients and Caregivers have also been revised to include information about safety obtained from post-authorization safety surveillance.

The physicians, and epidemiologists from FDA and CDC continuously screen and analyze VAERS data for COVID-19 vaccines to identify potential signals that would indicate the need for further study. This includes scientific consultation with neurologists and immunologists and our colleagues at the National Institutes of Health (NIH).

The analyses conducted by FDA include review of individual reports, aggregate analysis of VAERS data, and generating case series when indicated for possible safety concerns. In the course of these reviews, FDA has found that many reports do not represent side effects due to the vaccine. This may be because the diagnosis is not correct, medical records reveal the symptoms began prior to vaccination, or the patient has underlying medical conditions that explain the adverse event.

Decisions on whether there is some basis to believe there is a causal relationship are a matter of medical and scientific judgment and are based on factors such as: the frequency of reporting, biological plausibility, the timing of the event relative to the time of vaccination, and whether the adverse event is known to be caused by related vaccines. It is important to note that signals of rare adverse events can be detected, such as was the case in April 2021, when FDA and CDC physicians initially identified six serious adverse event reports (including 3 deaths) of thrombosis with thrombocytopenia syndrome (TTS) out of 6.8 million individuals that had been vaccinated with the Janssen COVID-19 vaccine.

FDA and CDC will continue to carefully monitor reports of all adverse event reports and [update](#) the public as more information becomes available.

Additional information of vaccine safety monitoring can be found on the web at the following links:

- [COVID-19 Vaccine Safety Surveillance | FDA](#)
- [Ensuring COVID-19 Vaccine Safety in the US | CDC](#)

From: Hunt, Alison <[REDACTED]>
Sent: Friday, January 28, 2022 3:23 PM
To: McNeill, Lorrie <[REDACTED]>
Cc: Capobianco, Abigail <[REDACTED]> Pfaeffle, Veronika <[REDACTED]>
Subject: RE: Media inquiry: Epoch Times, COVID-19 Vaccine Injury Research

Totally understood.

PSICOVID_00005519

Alison Hunt, MPH

Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel: [REDACTED] | Cell: [REDACTED]



From: McNeill, Lorrie <[REDACTED]>
Sent: Friday, January 28, 2022 3:22 PM
To: Hunt, Alison <[REDACTED]>
Cc: Capobianco, Abigail <[REDACTED]> Pfaeffle, Veronika <[REDACTED]>
Subject: RE: Media inquiry: Epoch Times, COVID-19 Vaccine Injury Research

We're working on these. But with everything else going on, they've not been our top priority. Will try to get back to you by the end of the day.

From: Hunt, Alison <[REDACTED]>
Sent: Friday, January 28, 2022 3:21 PM
To: McNeill, Lorrie <[REDACTED]>
Cc: Capobianco, Abigail <[REDACTED]> Pfaeffle, Veronika <[REDACTED]>
Subject: RE: Media inquiry: Epoch Times, COVID-19 Vaccine Injury Research

Hi Lorrie – checking in on this one as well.

Alison Hunt, MPH

Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel: [REDACTED] | Cell: [REDACTED]



From: Hunt, Alison
Sent: Wednesday, January 26, 2022 3:45 PM
To: McNeill, Lorrie <[REDACTED]>
Cc: Capobianco, Abigail <[REDACTED]> Pfaeffle, Veronika <[REDACTED]>
Subject: Media inquiry: Epoch Times, COVID-19 Vaccine Injury Research

Lorrie – given the specifics here, I'm not sure we can really answer this. I don't know what you all typically tell groups asking if we're looking into something. Would we want to say something about the neurological effects?

Reporter: Irene Luo

Outlet: Epoch Times

Deadline: 1/27 at 2pm ET

Questions:

We recently interviewed Brianne Dressen, co-founder of react19.org, and she says the FDA has failed to properly investigate what's happening to people injured by the COVID-19 vaccines like herself and Maddie de Garay, who was injured after her second dose in the Pfizer vaccine trial for kids.

She also noted that a lot of vaccine-injured individuals are being diagnosed and given medication for anxiety, instead of the actual underlying health issues, because doctors are afraid to recognize these ailments they suffer as related to the COVID-19 vaccines. She noted that after the myocarditis connection was communicated in public health messaging to public health officials, suddenly dozens of cases of vaccine-related myocarditis were identified.

PSICOVID_00005520

RE: Media inquiry: Epoch Times, neurologic symptoms from vaccines

From: "McNeill, Lorrie" <[REDACTED]>
To: "Hunt, Alison" <[REDACTED]>
Cc: "Capobianco, Abigail" <[REDACTED]> "Pfaeffle, Veronika" <[REDACTED]>
Date: Fri, 11 Feb 2022 14:44:45 -0500

Hi Alison –

Our response to the reporter is below. We don't have any information on what he's referring to in the question about Dr. Woodcock (Q5), so did not address in our response. We did not include the syncope language since that was included in the decision memo at the time of authorization.

If you have any questions, please let me know.

Lorrie

You asked about FDA's review of reported adverse events for autoimmune disorders. To date, the systems in place to monitor the safety of the COVID-19 vaccines authorized or approved for use in the U.S. have identified several health problems potentially associated with vaccination. These include [Guillain Barré syndrome](#) (a neurological disorder in which the body's immune system damages nerve cells, causing muscle weakness and sometimes paralysis) and [thrombosis with thrombocytopenia](#) (TTS) and immune thrombocytopenia (ITP) following the Janssen COVID-19 vaccine, and [myocarditis and pericarditis](#) following the Pfizer-BioNTech and Moderna COVID-19 vaccines. The chance of having these events occur is very low. To date, the systems for monitoring COVID-19 vaccine safety have not identified additional safety signals for serious neurological outcomes following COVID-19 vaccination.

The Fact Sheets for Healthcare Providers Administering Vaccine (Vaccination Providers) for each of the [COVID-19 vaccines](#) available for use in the U.S. have been revised to include information from post-authorization safety surveillance discussed above, including information in the Warning section pertaining to risks that have been identified. The Fact Sheets for Recipients and Caregivers have also been revised to include information about safety obtained from post-authorization safety surveillance.

The physicians, and epidemiologists from FDA and CDC continuously screen and analyze VAERS data for COVID-19 vaccines to identify potential signals that would indicate the need for further study. This includes scientific consultation with neurologists and immunologists and our colleagues at the National Institutes of Health (NIH).

The analyses conducted by FDA include review of individual reports, aggregate analysis of VAERS data, and generating case series when indicated for possible safety concerns. In the course of these reviews, FDA has found that many reports do not represent side effects due to the vaccine. This may be because the diagnosis is not correct, medical records reveal the symptoms began prior to vaccination, or the patient has underlying medical conditions that explain the adverse event.

Decisions on whether there is some basis to believe there is a causal relationship are a matter of medical and scientific judgment and are based on factors such as: the frequency of reporting, biological plausibility, the timing of the event relative to the time of vaccination, and whether the adverse event is known to be caused by related vaccines. It is important to note that signals of rare adverse events can be detected, such as was the case in April 2021, when FDA and CDC physicians initially identified six serious adverse event reports (including 3 deaths) of thrombosis with thrombocytopenia syndrome (TTS) out of 6.8 million individuals that had been vaccinated with the Janssen COVID-19 vaccine.

FDA and CDC will continue to carefully monitor reports of all adverse event reports and [update](#) the public as more information becomes available.

Additional information of vaccine safety monitoring can be found on the web at the following links:

- [COVID-19 Vaccine Safety Surveillance | FDA](#)
- [Ensuring COVID-19 Vaccine Safety in the US | CDC](#)

From: Hunt, Alison <[REDACTED]>
Sent: Friday, February 4, 2022 4:12 PM

PSICOVID_00005521

Su, John (CDC/NCEZID/DHQP/ISO)

From: Su, John (CDC/DDID/NCEZID/DHQP)
Sent: Tuesday, April 13, 2021 3:28 PM
To: Nair, Narayan; Mba-Jonas, Adamma (CBER) (FDA/CBER); Zinderman, Craig E (FDA/CBER); Alimchandani, Meghna (FDA/CBER); Woo, Jane (FDA/CBER); Ahima, Ohenewaa (FDA/CBER); Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP)
Subject: RE: Janssen - 4/13

I agree. To that end, does anybody have a proposed search strategy to identify such reports?

Last night, I tried "thrombosis", performed a second search for "thrombocytopenia" or "decreased platelet count", then took the two lists and looked for VAERS IDs that showed up in both lists – and got 13 results. 12 were after Moderna or Pfizer, and were non sequitur (e.g., sepsis, after immobilization x14 d, etc).

One report was after Janssen, and is the report Adamma references.

■ John

From: Nair, Narayan <[REDACTED]>
Sent: Tuesday, April 13, 2021 3:15 PM
To: Mba-Jonas, Adamma (CBER) (FDA/CBER) <[REDACTED]>; Zinderman, Craig E (FDA/CBER) <[REDACTED]>; Alimchandani, Meghna (FDA/CBER) <[REDACTED]>; Woo, Jane (FDA/CBER) <[REDACTED]>; Ahima, Ohenewaa (FDA/CBER) <[REDACTED]>; Su, John (CDC/DDID/NCEZID/DHQP) <[REDACTED]>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Subject: RE: Janssen - 4/13

Thanks Adamma and Craig,

I agree that this is a case of interest. I haven't had a chance to review the draft Brighton Collaboration Case definition in detail. But my thinking is we should consider any case with arterial or venous thrombosis with new onset thrombocytopenia/DIC as a case of interest.

I think we should
Narayan

From: Mba-Jonas, Adamma (CBER) <[REDACTED]>
Sent: Tuesday, April 13, 2021 3:06 PM
To: Zinderman, Craig E <[REDACTED]>; Alimchandani, Meghna <[REDACTED]>; Woo, Jane <[REDACTED]>; Ahima, Ohenewaa <[REDACTED]>; Nair, Narayan <[REDACTED]>; Su, John (CDC) <[REDACTED]>; Shimabukuro, Tom (CDC) <[REDACTED]>
Subject: Re: Janssen - 4/13

Right, this is what we were talking about last night on the CDC, that we should consider broadening what constitutes cases of interest...I would be in favor of considering this a case of interest.

Adamma

From: Zinderman, Craig E <[REDACTED]>
Sent: Tuesday, April 13, 2021 3:03:56 PM

To: Alimchandani, Meghna <[REDACTED]>; Woo, Jane <[REDACTED]>; Mba-Jonas, Adamma (CBER) <[REDACTED]>; Ahima, Ohenewaa <[REDACTED]>; Nair, Narayan <[REDACTED]>; Su, John (CDC) <[REDACTED]>; Shimabukuro, Tom (CDC) <[REDACTED]>
Subject: RE: Janssen - 4/13

Jane and others:

1197638 38F superior mesenteric artery thrombosis, bowel infarction, & DIC 6d after vacc; PMH morbid obesity

Would this case also be of concern?

Thanks,
Craig

From: Alimchandani, Meghna <[REDACTED]>
Sent: Tuesday, April 13, 2021 1:03 PM
To: Woo, Jane <[REDACTED]>; Mba-Jonas, Adamma (CBER) <[REDACTED]>; Ahima, Ohenewaa <[REDACTED]>; Nair, Narayan <[REDACTED]>; Su, John (CDC) <[REDACTED]>; Shimabukuro, Tom (CDC) <[REDACTED]>; Zinderman, Craig E <[REDACTED]>
Subject: RE: Janssen - 4/13

Jane, thank you for the summary. For the 3 cases 1198162, 1200573 and 1197665 – was there any info on plt #s/thrombocytopenia?

Thanks
Meghna

From: Woo, Jane <[REDACTED]>
Sent: Tuesday, April 13, 2021 12:59 PM
To: Mba-Jonas, Adamma (CBER) <[REDACTED]>; Ahima, Ohenewaa <[REDACTED]>; Alimchandani, Meghna <[REDACTED]>; Nair, Narayan <[REDACTED]>; Su, John (CDC) <[REDACTED]>; Zinderman, Craig E <[REDACTED]>
Subject: Janssen - 4/13

NB:

1198162 45F cerebral venous sinus thrombosis 7d after vacc; began with headache & vomiting; died 14d after vacc; PMH unknown (This case is from Mississauga, and it's NOT a duplicate of 1133212.)

1200573 56F died 9d after vacc; aneurysmal subarachnoid hemorrhage, cerebral herniation, malignant cerebral edema, and traumatic brain injury; PMH htn

1197665 48F subdural hematoma & R paralysis 1d after vacc; craniotomy; PMH DM; pt is the reporter, so she is able to read/write

The full list is below. Some people with clots had had recent surgery.

1168000 (old case) 50F myopericarditis & pericardial effusion 1 mo after vacc

1172292 (old case) 19M myopericarditis 1d after vacc

1195850 84M died 4-5 wks after vacc; unresponsive, hyperglycemia, & unable to swallow; had unspecified surgery and then developed post-op clots; PMH atrial fib, DM, & recent antibody treatment (unspecified) for dermatitis

1195949 59F anaphylaxis 11 min after vacc

1195956 29M vasovagal syncope; has had it after previous vacc

1196226 44F allergic reaction vs asthma exacerbation 1d after vacc

1196253 66F fever, chills, nausea, vomiting

1196332 47f chest pain, EKG changes, & elevated enzymes beginning <1d after vacc rule out MI

1196427 60M fatigue, chills, diarrhea, pain, & paresthesia beginning 1d after vacc

1196712 51F portal vein thrombosis a few days after vacc; had had recent cholecystectomy

1196901 63M dizziness, syncope, speech changes, & disorientation <1d after vacc; PMH cerebral palsy

1196925 42F headache, fever, chills, alaise, myalgia, dizziness, & anorexia beginning 30 min after vacc; had covid dz in Jan 2021

1197086 76F died 1d after vacc; had severe abdo pain & couldn't be resuscitated; PMH unknown

1197219 41F fever, chills, sz, myalgia, chest pain, visual changes, & headache; dx dystonic reaction

1197242 42M tinnitus 6h after vacc

1197476 41M fever, chills, dysgeusia, vomiting, & hallucinations <1d after vacc

1197479 72F GBS 11d after vacc on ventilator; PMH mild cognitive impairment

1197485 72M possible vaccine failure (serological) 17d after vacc

1197486 54F anaphylaxis 8 min after vacc

1197487 48M S. sap infection, headache, tinnitus, & epistaxis 2d after vacc

1197489 exacerbation of Ehlers Danlos

1197491 30F fever, chills, diaphoresis, sz, vomiting, & weakness <1d after vacc

1197500 44M syncope/dehydration & flu-like sx <1d after vacc

1197515 F (unknown age) exacerbation of pre-existing thrombocytopenia; lab values not reported; PMH "autoimmune deficiency syndrome"

1197517 29-yo (unknown sex) htn, palpitations, shakiness, & drowsiness 5 min after vacc

1197585 F (unknown age) hospitalized for unknown reason(s); poorly documented

1197638 38F superior mesenteric artery thrombosis, bowel infarction, & DIC 6d after vacc; PMH morbid obesity

1197646 57M covid infection 35d after vacc; PMH EtOH abuse, fatty liver, osteoarthritis

1197665 48F subdural hematoma & R paralysis 1d after vacc; craniotomy; PMH DM; pt is the reporter, so she is able to read/write

1197762 50F lower ext spasms 2d after vacc

1197801 18M probable myocarditis - chest pain, ST elevations, troponin 20.0, & CKMB elevated 2d after vacc; echo normal EF; recovered

1198043 63F Bell's palsy 23d after vacc; also fell

1198057 64M painful desquamating rash, possible SJS 1d after vacc; PMH htn, hyperlipidemia, allergic to sulfa, metronidazole, zetia & oxycontin

1198107 53F died 1 mo after vacc; covid infection 9d after vacc; new onset pneumonia, resp failure, DIC, renal failure; PMH asthma, renal insufficiency, DM, CHF, htn, hypothyroidism

1198135 25M fever, hemoptysis, arrhythmia, disorientation, chest tightness, abdominal pain, paresthesia beginning <1d after vacc; med error: received 2 doses (2 days apart)

1198147 78F CVA 9d after vacc; L MCA; received tPA; PMH eosinophilia

1198162 45F cerebral venous sinus thrombosis 7d after vacc; began with headache & vomiting; died 14d after vacc; PMH unknown

1198191 72M GBS 5d after vacc; on ventilator; PMH HTN, Type II DM, RA

1198227 76M died 4d after vacc; flu-like sx, anorexia, & AMS 2d after vacc; PMH DM, arthritis, unspecified heart dz

1198540 21M died 10d after vacc; found unresponsive, no sign of trauma; PMH unknown

1198691 80F weakness & slurred speech 2d after vacc; PMH unknown but pt on anticoagulant

1198771 59F paresthesia, slurred speech, & cramps 3d after vacc; labs, CT, MRI, CXR all normal; recovered

1198782 84F died 1-2d after vacc; sheriff said heart attack; PMH unknown

1199136 53F fever, paresthesia, & spasms beginning <1d after vacc

1199143 59F died 12d after vacc; hemorrhagic stroke 7-9d after vacc

1199203 51M bilateral PE 21d after vacc; PMH possible sleep apnea

1199984 62F DVT 18d after vacc; also "small pneumonia"

1200280 66F PE 19d after vacc; recovered; PMH htn & rheumatoid arthritis

1200303 25M petechiae, ecchymoses, & lightheadedness 7d after vacc; borderline htn, plt 194K

1200312 77M DVT/PE & pulmonary infarct 15d after vacc; PMH DM, htn, hyperlipidemia, COPD, recent hip surgery (Jan 2021)

1200343 38M appendicitis 4d after vacc

1200490 51M fever, chills, chest pain, dyspnea, myalgia, headache, & exhaustion 6d after vacc

1200493 78M headache, diaphoresis, L weakness, & fall 1-2d after vacc

1200514 61M died 1d after vacc; epistaxis (plt not reported)

1200564 65M died <1 wk after vacc; PMH CVA & htn

1200567 29F hematochezia beginning <1d after vacc; PMH unknown

1200572 58F CVA 7d after vacc; PMH none

1200573 56F died 3d after vacc; aneurysmal subarachnoid hemorrhage, cerebral herniation, malignant cerebral edema, anoxic brain injury; PMH htn

1200615 74F ischemic CVA 4h after vacc; PMH DM, RA, Hyperthyroidism, OSA, depression

1200648 52M DVT 16d after vacc

Produced to Senate Homeland Security & Governmental Affairs Committee Permanent Subcommittee on Investigations
Do Not Disclose Without Permission from Department of Health and Human Services

From: Marks, Peter [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DFBB2B5BD38445CB9C9ADCA3F72DF53A-MARKSP]
Sent: 1/21/2023 12:53:18 PM
To: Walensky, Rochelle P (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df848b046e3947be9b8809afe76917e9-HHS-aux7-cd]; Berger, Sherri (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2b1ac8b1b9ba4abe8ef7b1d7abcd8d71-HHS-sob8-cd]; Goldstein, Robert H (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bf60eafa00024febb5d482f6cf371f9c-HHS-qyd2-cd]; Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]; Califf, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad88732be1ed4912a058ee9dd9906f66-Robert.Califf]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodcock]; Griffis, Kevin C (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f48996703cb340e7a1a196581f0dfe8b-Contact_6df]; Shimabukuro, Tom (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8313741a075c4f3d8d8351e106d1ffb-HHS-ayv6-cd]; Helfand, Rita (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae435981a2b14a1d8b16cfd4c9545751-HHS-rzh7-cd]
Subject: RE: [EXTERNAL] CDC/FDA Call
Attachments: Booster analysis 012123.pptx

Dear All,

Please see this slide set for reference purposes this afternoon. The information on the FDA analysis is updated.

Best Regards,
Peter

-----Original Appointment-----

From: Walensky, Rochelle (CDC/OD) [REDACTED]
Sent: Saturday, January 21, 2023 12:21 PM
To: Walensky, Rochelle (CDC/OD); Berger, Sherri (CDC); Goldstein, Robert H (CDC); Tierney, Julia; Califf, Robert; Marks, Peter; Woodcock, Janet; Griffis, Kevin C (CDC); Shimabukuro, Tom (CDC); Helfand, Rita (CDC)
Subject: [EXTERNAL] CDC/FDA Call
When: Saturday, January 21, 2023 5:30 PM-6:00 PM (UTC-05:00) Eastern Time (US & Canada).
Where: Zoom link below

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hi there,

Lynn Gershman is inviting you to a scheduled Zoom meeting.

Join Zoom Meeting

One tap US: [REDACTED]

mobile:

Meeting [REDACTED]

URL:

Meeting [REDACTED]

ID:

Passcode:0sd*5eaC

Join by Telephone

For higher quality, dial a number based on your current location.

Dial: + [REDACTED] US (San Jose)
+ [REDACTED] US (US Spanish Line)
+ [REDACTED] US (New York)
+ [REDACTED] US
+ [REDACTED] US (San Jose)
[REDACTED] US (US Spanish Line)

Meeting [REDACTED]

ID:

Passcode [REDACTED]

International numbers

Join from an H.323/SIP room system

H.323: [REDACTED]

Meeting [REDACTED]

ID:

Passcode [REDACTED]

SIP: [REDACTED]

Passcode [REDACTED]

Skype for Business (Lync)

[REDACTED]



U.S. FOOD & DRUG
ADMINISTRATION

Update on COVID-19 Vaccine Safety

Confidential

Presentation currently includes bivalent results with the following data cuts:

CMS - data through 12/24

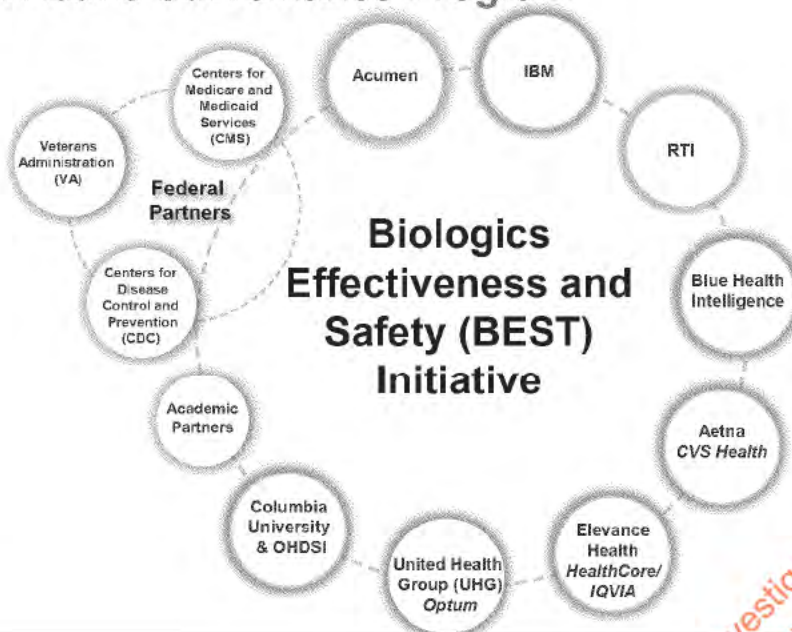
HCI - data through 11/7

CVS - data through 10/31

Optum data are not currently included

Produced to Homeland Security and Government Affairs Permanent Subcommittee on Investigations Pursuant to Oversight Request
Do Not Disclose Without Permission from U.S. Department of Health and Human Services

CBER Active Surveillance Program



Produced to Homeland Security and Government Affairs Permanent Subcommittee on Investigations Pursuant to Oversight Request
Do Not Disclose Without Permission from U.S. Department of Health and Human Services

BEST Initiative Data Sources



Data Source*	Database Type	No. Patients Covered (Millions)	Time Period Covered
CMS- Medicare	Claims	105	2005 - present
MarketScan Commercial and Medicare Supplemental	Claims	254	1999 - 2019
MarketScan Medicaid	Claims	48	1999 - 2019
MarketScan Commercial (IBM)	Claims	65	2016 - present
Blue Health Intelligence	Claims	93	2016 - present
Optum - Adjudicated	Claims	66	1993 - present
Optum - Pre adjudicated	Claims	31	2017 - present
HealthCore	Claims	70	2010 - present
CVS Health	Claims	41	2018 - present
OneFlorida Clinical Research Consortium - Medicaid	Claims	6.7	2012 - present
OneFlorida Clinical Research Consortium - EHR	EHR	5.8	2012 - present
Optum EHR	EHR	102	2007 - 2020
MedStar Health Research Institute	EHR	6	2009 - present
PEDSnet	EHR	6.2	2009 - present
IBM CED	Linked EHR Claims	5.4	2000 - present
Optum Integrated Claims - EHR	Linked EHR Claims	25	2007 - 2020

*Data lag varies based on data source, ranges from a few days to a few months.

Produced to Homeland Security and Government Affairs Permanent Subcommittee on Investigations Pursuant to Oversight Request
Do Not Disclose Without Permission from U.S. Department of Health and Human Services

COVID-19 Bivalent mRNA Vaccines Rapid Cycle Analyses Administered Doses By Age Group

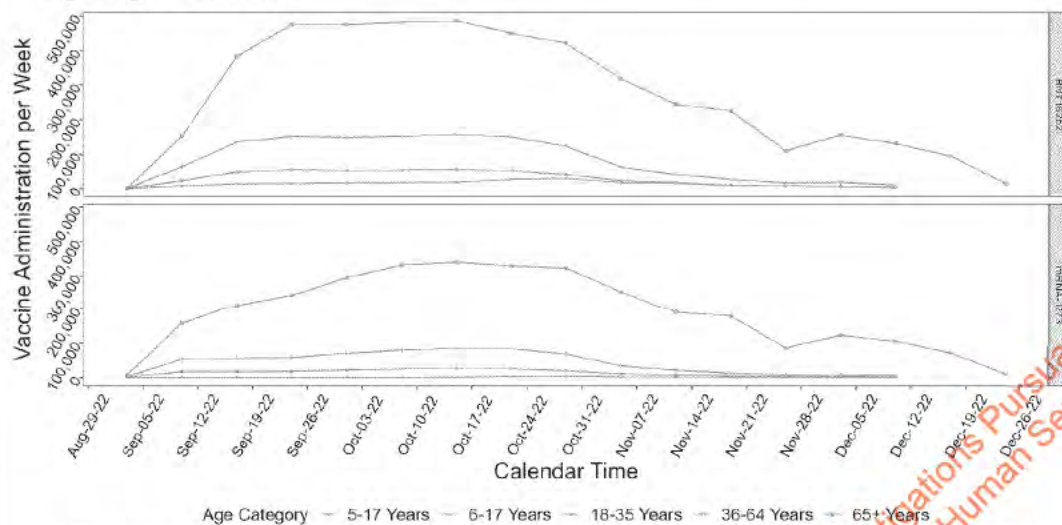


Age Groups (years)	BNT162b2 (# vaccinations)	mRNA-1273 (# vaccinations)	Total (# vaccinations)
5/6-17 ¹	196,992	13,016	210,008
18-35 ¹	442,870	211,694	654,564
36-64 ¹	1,248,430	654,220	1,902,650
65+ ²	4,265,244	3,042,074	7,307,318

1. Data cuts: CVS data through 10/2022, HealthCore data through 11/2022, Optum data through 12/2022
2. Data cuts: CMS data through 12/2022

Produced to Homeland Security and Government Affairs Permanent Subcommittee on Investigations Pursuant to Oversight Request
Do Not Disclose Without Permission from U.S. Department of Health and Human Services

COVID-19 Bivalent mRNA Vaccines Doses Administered By Age Group



Produced to Homeland Security and Government Affairs Permanent Subcommittee on Investigations Pursuant to Oversight Request
Do Not Disclose Without Permission from U.S. Department of Health and Human Services

COVID-19 Bivalent mRNA Vaccines Safety Monitoring

- **Study Design:** Rapid Cycle Analysis (RCA) near real-time surveillance
 - No causal association established
- **Population:** 0-4/5 years, 5/6-17 years, 18-64 years*, ≥65 years
- **Exposure:** mRNA-1273.222 and BNT162b2 COVID-19 vaccines
 - Bivalent booster: original SARS-CoV-2 virus and Omicron variants BA.4 and BA.5.
- **Statistical Method:** MaxSPRT
- **Comparator:** Historical rates

*For the myocarditis/pericarditis outcome, the study population was additionally split into 18-35 and 36-64 year age groups.

6

Note that results for 0-5/6 years old are not included in presentation as monitoring is still being set up for this population

Produced to Homeland Security and Government Affairs Permanent Subcommittee on Investigations Pursuant to Oversight Request
Do Not Disclose Without Permission from U.S. Department of Health and Human Services

Adverse Events Monitored

FDA

Adverse Events Monitored in Adult and Pediatric Populations	
Acute Myocardial Infarction	Hemorrhagic Stroke
Anaphylaxis	Immune Thrombocytopenia
Appendicitis	Multisystem Inflammatory Syndrome
Bell's Palsy	Myocarditis/Pericarditis (Myo-/Pericarditis)*
Common Site Thrombosis with Thrombocytopenia	Narcolepsy
Disseminated Intravascular Coagulation	Non-hemorrhagic Stroke
Deep Vein Thrombosis	Pulmonary Embolism
Encephalitis/Encephalomyelitis	Transverse Myelitis
Guillain-Barre Syndrome	Unusual Site Thrombosis (Broad) with Thrombocytopenia

Adverse Events Monitored in Pediatric Populations Only
Seizure/Febrile Seizure
Kawasaki Disease
Multisystem Inflammatory Syndrome in children (MIS-C)

*This includes 4 myo-/pericarditis outcome definitions varying care settings (all settings vs. IP/OP-ED) and risk windows (2-7 vs. 1-21 days)
These AEs have not been associated with COVID-19 vaccines based on available pre-licensure evidence.

7

Multisystem Inflammatory Syndrome in children (MIS-C) was in the previous version

Produced to Homeland Security and Government Affairs Permanent Subcommittee on Investigations Pursuant to Oversight Request
Do Not Disclose Without Permission from U.S. Department of Health and Human Services

Signals Detected



Adverse Event (AE)	Medicare Population ¹ (Ages 65+)	Adult Population ² (Ages 18-64)	Pediatric Population ² (Ages 5-17/6-17)
Acute Myocardial Infarction	No	No	Descriptive Only
Anaphylaxis	No	No	No
Appendicitis	No	No	No
Disseminated Intravascular Coagulation	No	No	No
Deep Vein Thrombosis	No	No	No
Bell's Palsy	No	No	No
Encephalomyelitis/Encephalitis	No	No	No
Guillain-Barré Syndrome	No	No	Descriptive Only
Hemorrhagic Stroke	No	No	Descriptive Only
Myocarditis/Pericarditis	No	BNT162b2 Bivalent (18-35)	No
Common Site Thrombosis with Thrombocytopenia	No	No	No
Uncommon Site Thrombosis with Thrombocytopenia Syndrome	No	No	Descriptive Only
Narcolepsy	No	No	No
Non-Hemorrhagic Stroke	No	No	No
Pulmonary Embolism	No	No	No
Transverse Myelitis	No	No	Descriptive Only
Immune Thrombocytopenia	No	No	No
Febrile Seizures	N/A	N/A	Descriptive Only
Seizures/Convulsions	N/A	N/A	No
Kawasaki disease	N/A	N/A	Descriptive Only
Multisystem Inflammatory Syndrome	Descriptive Only	Descriptive Only	Descriptive Only

Data cut: CMS 12/2022

Health Care Data through 10/2022; Health Care Data through 11/2022; Optum Data through 12/2022

AEs and the associated vaccine brand with a safety signal are noted.

N/A indicates neither descriptive monitoring nor sequential testing is being conducted in the indicated age group for a given AE. NO indicates that a safety signal has not been detected. Descriptive Only indicates sequential testing is not being conducted in the indicated age group for a given AE.

Produced to Homeland Security and Government Affairs Permanent Subcommittee on Investigations Pursuant to Oversight Request
Do Not Disclose Without Permission from U.S. Department of Health and Human Services

Concomitant Influenza Vaccination



- Approximately 4.25 million doses of the Pfizer-BioNTech bivalent vaccine have been administered in the CMS database in individuals 65 years and older
- Rate of influenza vaccination is about 40%, majority either high dose or adjuvanted
- Further work to be done to segment out the different influenza vaccine types administered with the COVID-19 vaccines
- No signal seen at this time for non-hemorrhagic stroke

Produced to Homeland Security and Government Affairs Permanent Subcommittee on Investigations Pursuant to Oversight Request
Do Not Disclose Without Permission from U.S. Department of Health and Human Services

COVID-19 Bivalent mRNA Vaccines RCA Summary



- This is a large-scale signal detection study of two COVID-19 mRNA bivalent vaccines conducted in multiple claims databases.
- Among adults 65 years and older, several AEs have completed the surveillance period. No signal at this time for non-hemorrhagic stroke
- Signal detection studies do not establish a causal relationship and further evaluation of signals is required in more robust studies.

Produced to Homeland Security and Government Affairs Permanent Subcommittee on Investigations Pursuant to Oversight Request
Do Not Disclose Without Permission from U.S. Department of Health and Human Services

International Reports Have Not Signaled for Stroke



- FDA contacted other regulators around the world to learn whether anyone had seen safety signals for stroke, vascular events, or thromboembolic events with bivalent boosters
- No regulatory body reported a signal that any of these events may be associated with mRNA bivalent COVID-19 vaccines
- The following bodies specifically reported that they had not seen a signal: Israel, Japan, Germany, EMA, Italy, UK, and Canada

Produced to Homeland Security and Government Affairs Permanent Subcommittee on Investigations Pursuant to Oversight Request
Do Not Disclose Without Permission from U.S. Department of Health and Human Services

Data Suggesting Absence of Safety Risk



- 1) Further analysis of VSD data reveals absence of signal in alternate analyses and potential confounders identified for initial signal
- 2) No excess reports of stroke from VAERS
- 3) CMS database with about 4.25 million doses shows no increase in stroke
- 4) VA database run shows no increase in stroke on preliminary query
- 5) Various countries in Europe as well as Israel indicate no increased risk of stroke in their surveillance systems
- 6) Pfizer notes no increase in signal in their global safety database or when comparing the monovalent to bivalent vaccines

In any case, a formal epidemiologic study is being initiated by FDA to prepare for potential vaccine coadministration in 2023-2024

Produced to Homeland Security and Government Affairs Permanent Subcommittee on Investigations Pursuant to Oversight Request
Do Not Disclose Without Permission from U.S. Department of Health and Human Services

Cc: Nair, Narayan (FDA/CBER) <[REDACTED]> Mba-Jonas, Adamma (CBER) (FDA/CBER) <[REDACTED]> Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Subject: RE: [EXTERNAL] RE: Janssen COVID-19 Vaccine myocarditis/pericarditis cases

Hi Meghna,

I hope you are doing well. For Janssen 64 of 93 occurred in the 21-day risk window

Thanks

Pedro

From: Alimchandani, Meghna <[REDACTED]>
Sent: Monday, March 6, 2023 1:17 PM
To: Woo, Jane (FDA/CBER) <[REDACTED]> Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Cc: Nair, Narayan (FDA/CBER) <[REDACTED]> Mba-Jonas, Adamma (CBER) (FDA/CBER) <[REDACTED]> Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Subject: RE: [EXTERNAL] RE: Janssen COVID-19 Vaccine myocarditis/pericarditis cases

Pedro,

For the CDC dataset on 93 cases of myocarditis and pericarditis after Janssen, will you be able to share some information on the time to onset...how many of these cases occurred in the 21-day risk window?

Thanks!

Best regards,
Meghna

From: Alimchandani, Meghna
Sent: Wednesday, February 22, 2023 9:41 AM
To: Woo, Jane <[REDACTED]> Moro, Pedro L (CDC) <[REDACTED]>
Cc: Nair, Narayan <[REDACTED]> Mba-Jonas, Adamma (CBER) <[REDACTED]> Shimabukuro, Tom (CDC) <[REDACTED]>
Subject: RE: [EXTERNAL] RE: Janssen COVID-19 Vaccine myocarditis/pericarditis cases

Many many thanks, Pedro, for your speedy response! The information you provided in your email is very helpful! Thank you so much.

Best regards,
Meghna

From: Woo, Jane <[REDACTED]>
Sent: Tuesday, February 21, 2023 5:07 PM

To: Moro, Pedro L (CDC) <[REDACTED]> Alimchandani, Meghna <[REDACTED]>
Cc: Nair, Narayan <[REDACTED]> Mba-Jonas, Adamma (CBER) <[REDACTED]>
[REDACTED] Shimabukuro, Tom (CDC) <[REDACTED]>
Subject: RE: [EXTERNAL] RE: Janssen COVID-19 Vaccine myocarditis/pericarditis cases

Thank you!

From: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Sent: Tuesday, February 21, 2023 4:57 PM
To: Alimchandani, Meghna <[REDACTED]> Woo, Jane <[REDACTED]>
Cc: Nair, Narayan <[REDACTED]> Mba-Jonas, Adamma (CBER) <[REDACTED]>
[REDACTED] Shimabukuro, Tom (CDC) <[REDACTED]>
Subject: [EXTERNAL] RE: Janssen COVID-19 Vaccine myocarditis/pericarditis cases

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hi Meghna,

As of 02/16/2023 we have 93 (61 myocarditis and 32 pericarditis) reports after Janssen that met CDC case definition. 31 were aged <30 years . 92 were after dose 1 and 1 after dose 2 (received Pfizer for dose 1).

I have some of the same deaths: 1667385, 1779444, 1972052, 1223941, 1481541, 1365209, 1463070

We abstract the reports and reviewed to see which met case definition but we don't really review the cases to see if myopericarditis was the cause of death

Thanks

Pedro

1172292

1204923

1207403

1207772

1216418

1221058

1223941

1227834

1255988

1262490

1269149

1274222

1301219

1307303

1333503

1343980

1348644

1350424

1350646

1357976

1365209

1372039

1377901

1382281

1391773

1394380

1400273

1403355

1403411

Produced to Homeland Security and Government Affairs Permanent Subcommittee on Investigations Pursuant to Oversight Request
Do Not Disclose Without Permission from U.S. Department of Health and Human Services

1408664

1410318

1417921

1425280

1429815

1432533

1433407

1459911

1460236

1463070

1464673

1465771

1466553

1478366

1478495

1481541

1490649

1500944

1502170

1515244

1515314

1536049

1591510

1617821

Produced to Homeland Security and Government Affairs Permanent Subcommittee on Investigations Pursuant to Oversight Request
Do Not Disclose Without Permission from U.S. Department of Health and Human Services

1656161

1667385

1671372

1693631

1716785

1720693

1726656

1731144

1740847

1741713

1755733

1765512

1779444

1786193

1794223

1795765

1804186

1813351

1821442

1846880

1855071

1859034

1876723

1881097

1896520

1951190

1963286

1967234

1972052

1985757

2019925

2046250

2051338

2080292

2147368

2152384

2263245

2373691

2504616

1546334

From: Alimchandani, Meghna <[REDACTED]>
Sent: Tuesday, February 21, 2023 12:41 PM
To: Woo, Jane (FDA/CBER) <[REDACTED]> Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Cc: Nair, Narayan (FDA/CBER) <[REDACTED]> Mba-Jonas, Adamma (CBER) (FDA/CBER) <[REDACTED]> Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Subject: RE: Janssen COVID-19 Vaccine myocarditis/pericarditis cases

Thanks, Jane, for sending these.

Pedro, if there are additional fatal cases in your dataset of confirmed myo/peri for Janssen, please let us know. Thanks!

Best,

Meghna

From: Woo, Jane <[REDACTED]>
Sent: Tuesday, February 21, 2023 11:50 AM
To: Alimchandani, Meghna <[REDACTED]> Moro, Pedro L (CDC) <[REDACTED]>
Cc: Nair, Narayan <[REDACTED]> Mba-Jonas, Adamma (CBER) <[REDACTED]> Shimabukuro, Tom (CDC) <[REDACTED]>
Subject: RE: Janssen COVID-19 Vaccine myocarditis/pericarditis cases

FYI - we already know about these fatal cases:

1223941 (confirmed)

30M myocarditis & died 8d after vacc; DC: sudden cardiac death, cardiomegaly with dilatation, mild focal myocarditis, focal myocardial fibrosis; 1421333 = 1223941

1459756

55F pericarditis & large vessel vasculitis 11d after vacc; died 22d after vacc; PMH DM
autopsy: "COD: sepsis with pericarditis and large vessel vasculitis due to S aureus bacterial infection; other significant conditions: recent SARS-CoV-2 vaccination and diabetes mellitus."
Path dx: "sepsis...pericarditis with large vessel vasculitis, fibrinous exudate covering pericardial surface, approximately 200 mL of pink, thick fluid within pericardial sac, dusky discoloration of brachiocephalic and left common carotid arteries...histologically demonstrable full thickness fibrinoid necrosis of arterial walls...aorta fibrinous exudate on adventitial surface at takeoff...right radial artery fibrinoid material and associated inflammatory cells within adventitial vessel
Microscopic evaluation of heart: moderate chronic inflammation of the epicardium. Myocyte hypertrophy with mild interstitial fibrosis.

1481541 (confirmed)

68F sudden cardiac death 4d after vacc; autopsy noted myocarditis as the most significant anatomic finding; PMH endometrial ca, saddle PE (2020)

Autopsy: final path dx: cardiovascular myocarditis, mild aortic atherosclerosis;
myocardium: patchy interstitial infiltrates of variable composition (lymphocytes, plasma cells, eosinophils) focally associated with myocyte degenerative changes

1549143

67F pericarditis <1d after vacc (interval unclear) & died 5 wks after vacc; PMH htn, COPD;
DC: atherosclerotic cardiovascular disease

1667385 (confirmed)

69M myocarditis & died 3 mo after vacc; autopsy reportedly says myocarditis from viral infection; initial sx "normal side effects"; PMH htn, hld; after data lock point
9/2/22 still trying to obtain autopsy report

1779444 (confirmed)

55F myocarditis & died 6d after vacc; report is from medical examiner; PMH migraines & chronic bronchitis

Autopsy: cause of death myocarditis; enlarged myocytes with enlarged irregular hyperpigmented nuclei, scattered aggregates of chronic inflammatory cell infiltrates, interstitial edema, mild interstitial perivascular fibrosis

"The subject died as the result of myocarditis (myocardial infiltrate at the AV node area of the interventricular cardiac septum)."

From: Alimchandani, Meghna <[REDACTED]>
Sent: Tuesday, February 21, 2023 11:33 AM
To: Moro, Pedro L (CDC) <[REDACTED]>
Cc: Nair, Narayan <[REDACTED]> Mba-Jonas, Adamma (CBER) <[REDACTED]>
[REDACTED] Woo, Jane <[REDACTED]> Shimabukuro, Tom (CDC) <[REDACTED]>
Subject: Janssen COVID-19 Vaccine myocarditis/pericarditis cases

Hi Pedro,

We are having ongoing discussions re cases of **myocarditis and pericarditis** after the **Janssen COVID-19 Vaccine**.

You had previously sent us a list, containing 86 myocarditis and pericarditis cases, as of *November 10, 2022* data lock point.

- 86 reports met CDC case definition, 58 for myocarditis and 28 for pericarditis
- 27 patients were < 30 years (18-29 years) and 59 were ≥ 30 years (30-76 years)

We have two requests for CDC:

- Will you be able to send us updated data on the myocarditis and pericarditis cases after Janssen COVID-19 Vaccine, with the most recent data lock point you have?
- For cases with fatal outcome, will you be able share the clinical details, and comment on whether the death was attributed to myocarditis (if that information is available).

Thank you so much!

Others from FDA, please chime in if I missed anything.

Best regards,
Meghna

From: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Sent: Monday, November 21, 2022 12:45 PM
To: Alimchandani, Meghna <[REDACTED]>
Cc: Nair, Narayan <[REDACTED]> Mba-Jonas, Adamma (CBER) <[REDACTED]>
[REDACTED]
Subject: RE: [EXTERNAL] RE: Janssen COVID-19 Vaccine myocarditis/pericarditis cases

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hi Meghna,

We were doing enhanced surveillance for <30 initially meaning that CDC would get the records or call the provider. This was then changed (around February or March 2022) to <18 years and it is still being done now. When I review cases to see which met case definition I do it for all brands and ages but of course for the counts I just report the numbers for <18 years.

Pedro

From: Alimchandani, Meghna <[REDACTED]>
Sent: Monday, November 21, 2022 12:31 PM
To: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Cc: Nair, Narayan (FDA/CBER) <[REDACTED]> Mba-Jonas, Adamma (CBER) (FDA/CBER) <[REDACTED]>
Subject: RE: [EXTERNAL] RE: Janssen COVID-19 Vaccine myocarditis/pericarditis cases

Hi Pedro,

Quick question: For adjudication of the Janssen myocarditis cases, did CDC preferentially review cases below age 30 years? I believe for the mRNA vaccine cases, the team was preferentially reviewing the reports in younger age groups given the increased risk in those ages. Was a similar approach followed during adjudication for Janssen cases?

From the Janssen myo/peri data, it does not seem that there is a trend with regards to age or sex predilection.

Thanks
Meghna

From: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Sent: Monday, November 14, 2022 12:19 PM
To: Alimchandani, Meghna <[REDACTED]>
Cc: Su, John (CDC) <[REDACTED]> Mba-Jonas, Adamma (CBER) <[REDACTED]>
Nair, Narayan <[REDACTED]>
Subject: RE: [EXTERNAL] RE: Janssen COVID-19 Vaccine myocarditis/pericarditis cases

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Yes, November 10

Pedro

From: Alimchandani, Meghna <[REDACTED]>
Sent: Monday, November 14, 2022 12:17 PM
To: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Cc: Su, John (CDC/DDID/NCEZID/DHQP) <[REDACTED]> Mba-Jonas, Adamma (CBER) (FDA/CBER) <[REDACTED]> Nair, Narayan (FDA/CBER) <[REDACTED]>
Subject: RE: [EXTERNAL] RE: Janssen COVID-19 Vaccine myocarditis/pericarditis cases

Thanks so much, Pedro, for your quick response!
Got it. Really appreciate the info on the myo/peri cases validated by CDC for Janssen. This data is through 11/10/22, correct?

Thanks
Meghna

From: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Sent: Monday, November 14, 2022 12:16 PM
To: Alimchandani, Meghna <[REDACTED]>
Cc: Su, John (CDC) <[REDACTED]> Mba-Jonas, Adamma (CBER) <[REDACTED]> Nair, Narayan <[REDACTED]>
Subject: RE: [EXTERNAL] RE: Janssen COVID-19 Vaccine myocarditis/pericarditis cases

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hi Meghna,

We don't have data on outcome/recovery. The project that followed cases of myopericarditis involved mRNA COVID-19 vaccines as far as I am concerned. The median onset was 8 days (0-180 days) with a IQR= 12 days for 71 reports with onset interval data

The VAERS Ids are below

Thanks

Pedro

1172292

1204923

1207403

1207772

1216418

1221058

1223941

1227834

1255988

1262490

1269149

1274222

1301219

1307303

1333503

1343980

1348644

1350424

1350646

1357976

1365209

1372039

1377901

1382281

1391773

1394380

1400273

1403411

1408664

Produced to Homeland Security and Government Affairs Permanent Subcommittee on Investigations Pursuant to Oversight Request
Do Not Disclose Without Permission from U.S. Department of Health and Human Services

1410318

1417921

1425280

1429815

1432533

1433407

1459911

1460236

1463070

1464673

1465771

1466553

1478366

1478495

1490649

1500944

1502170

1515244

1515314

1536049

1591510

1617821

1656161

1671372

1693631

1716785

1720693

1726656

1731144

1740847

1741713

1755733

1765512

1786193

1794223

1795765

1813351

1821442

1846880

1855071

1859034

1876723

1881097

1896520

1963286

1967234

1972052

1985757

Produced to Homeland Security and Government Affairs Permanent Subcommittee on Investigations Pursuant to Oversight Request
Do Not Disclose Without Permission from U.S. Department of Health and Human Services

2051338

2147368

2263245

1403355

1804186

2019925

2046250

2080292

2152384

From: Alimchandani, Meghna <[REDACTED]>
Sent: Monday, November 14, 2022 9:27 AM
To: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Cc: Su, John (CDC/DDID/NCEZID/DHQP) <[REDACTED]> Mba-Jonas, Adamma (CBER) (FDA/CBER) <[REDACTED]> Nair, Narayan (FDA/CBER) <[REDACTED]>
Subject: RE: [EXTERNAL] RE: Janssen COVID-19 Vaccine myocarditis/pericarditis cases

Thank you so much, Pedro.

This is extremely helpful!

Not sure if you have additional data on the following, if available, please share with us:

- Data on outcome/recovery for the 86 Janssen reports that met case definition?
- Data on time to onset for myo or peri for these reports?

Can you also give us the list of VAERS IDs for the 86 reports?

Thanks!

Best regards,
Meghna

From: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Sent: Thursday, November 10, 2022 9:00 PM
To: Alimchandani, Meghna <[REDACTED]>
Cc: Su, John (CDC) <[REDACTED]> Mba-Jonas, Adamma (CBER) <[REDACTED]> Nair, Narayan <[REDACTED]>
Subject: RE: [EXTERNAL] RE: Janssen COVID-19 Vaccine myocarditis/pericarditis cases

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hi Meghna,

There are 86 reports that met case definition, 58 for myocarditis and 28 for pericarditis, after the JJ vaccine. There were 2 reports not included here where the person received JJ for the first dose and a mRNA vaccine for a second or third dose and the myo or pericarditis occurred after that other mRNA. In terms of age breakdown among the 86, 27 were < 30 years (18-29 years) and 59 were >=30 years (30-76 yrs)

Have a nice weekend

Pedro

From: Alimchandani, Meghna <[REDACTED]>
Sent: Wednesday, November 9, 2022 3:39 PM
To: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[REDACTED]>
Cc: Su, John (CDC/DDID/NCEZID/DHQP) <[REDACTED]> Mba-Jonas, Adamma (CBER) (FDA/CBER) <[REDACTED]> Nair, Narayan (FDA/CBER) <[REDACTED]>
Subject: RE: [EXTERNAL] RE: Janssen COVID-19 Vaccine myocarditis/pericarditis cases

Yes, tomorrow would be totally fine. If you could include the case counts specific for Janssen, that would be great. thanks!

Meghna

From: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <ps[REDACTED]>
Sent: Wednesday, November 9, 2022 3:33 PM
To: Alimchandani, Meghna <[REDACTED]>
Cc: Su, John (CDC) <[REDACTED]>; Mba-Jonas, Adamma (CBER) <[REDACTED]>
Nair, Narayan <[REDACTED]>
Subject: [EXTERNAL] RE: Janssen COVID-19 Vaccine myocarditis/pericarditis cases

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hi Meghna,

I'll be happy to. I was going to update the counts tomorrow which is the day I typically do it. Would it be ok if I send you the information tomorrow?

Thanks

Pedro

From: Alimchandani, Meghna <[REDACTED]>
Sent: Wednesday, November 9, 2022 3:29 PM
To: Moro, Pedro (CDC/DDID/NCEZID/DHQP) <[REDACTED]>

Cc: Su, John (CDC/DDID/NCEZID/DHQP) <[REDACTED]> Mba-Jonas, Adamma (CBER) (FDA/CBER)
<[REDACTED]> Nair, Narayan (FDA/CBER) <[REDACTED]>
Subject: Janssen COVID-19 Vaccine myocarditis/pericarditis cases

Hi Pedro,

We have been asked to provide an update on myo/peri cases after Janssen.

Would you be able to let us know the updated case counts for the number of Janssen myo/pericarditis cases confirmed by CDC, and the number of Janssen myo/peri cases that remain under review?

Thanks!

Best regards,
Meghna

Produced to Homeland Security and Government Affairs Permanent Subcommittee on Investigations Pursuant to Oversight Request
Do Not Disclose Without Permission from U.S. Department of Health and Human Services

From: [Walke, Henry \(CDC/OD/ORR/OD\)](#)
To: [Walensky, Rochelle \(CDC/IOD\)](#)
Subject: DRAFT_Myocarditis_Advisory_05232021_1109
Date: Sunday, May 23, 2021 1:12:18 PM
Attachments: [DRAFT_Myocarditis_Advisory_05232021_1109.docx](#)

Latest HAN.

Produced to Homeland Security and Government Affairs Permanent Subcommittee on Investigations Pursuant to Oversight Request
Do Not Disclose Without Permission from U.S. Department of Health and Human Services

Summary

In recent weeks, occasional cases of mild myocarditis and pericarditis have been reported in the United States after mRNA COVID-19 vaccination, particularly in adolescents and young adults. To date, the number of reports is small given the number of vaccine doses administered; most cases were mild and patients have responded well to conservative treatment (e.g., NSAIDs, rest). CDC and its partners are actively investigating these reports to assess for any relationship to vaccination. CDC recommends that healthcare providers 1) consider myocarditis and pericarditis in adolescents and young adults with acute chest pain, shortness of breath, or palpitations following recent COVID-19 vaccination and consider consultation with cardiology and infectious disease and/or rheumatology for suspected cases of myocarditis and pericarditis, and 2) report any suspected cases to the [Vaccine Adverse Event Reporting System \(VAERS\)](#). The benefit of vaccination in preventing acute and chronic complications of COVID-19 in this population outweighs the risk of occasional and mild myocarditis and pericarditis. CDC continues to recommend [COVID-19 vaccination](#) for individuals 12 years or older. The risk of COVID-19 illness and related, potentially severe, complications.

Background

Myocarditis is the inflammation of the heart muscle, and pericarditis is the inflammation of the lining outside of the heart. Common symptoms may include chest pain, shortness of breath, or palpitations. Cases of acute myocarditis include those with symptoms not attributable to another cause and at least one of the following: elevated biomarkers of cardiac injury (e.g. troponin), electrocardiogram (ECG or EKG) or cardiac magnetic resonance imaging (cMRI) findings suggestive of cardiac injury, or abnormal cardiac function on echocardiogram or cMRI.^{1,2} Acute pericarditis includes patients with at least two of the following: acute chest pain, pericardial rub on exam, new ST-elevation or PR-depression on ECG, or new or worsening pericardial effusion.³ When myocarditis and pericarditis present together, as is often the case, the term myopericarditis is used.

Myocarditis and pericarditis are frequently attributed to seasonal viral infections, although the specific virus is often not identified. In most cases, patients respond to conservative treatment (e.g., NSAIDs, rest), but other treatments may be required for more severe cases. Patients can typically return to normal activity after initial improvement in symptoms; for those with myocarditis or myopericarditis, even mild, restriction from rigorous athletic activity is recommended for at least 3 months.⁴

CDC is monitoring VAERS for possible cases of myocarditis and pericarditis following vaccination since the initial authorization of COVID-19 vaccines. Based on reports to VAERS, cases have occurred:

- predominantly in adolescents and young adults,
- more often in males than females,
- following both Pfizer-BioNTech and Moderna mRNA COVID-19 vaccines,
- more often following dose 2 than dose 1, and
- typically within a week after vaccination.

To date, the number of reports is small given the number of vaccine doses administered, and most cases have been mild and responded quickly with appropriate medical care. Additional follow-up is ongoing to understand the clinical characteristics of these cases and possible risk factors and to assess for any possible relationship to vaccination. CDC will continue to monitor for and evaluate reports of myocarditis and pericarditis occurring after COVID-19 vaccination and will share more information as it becomes available.

Recommendations for Clinicians

- Myocarditis or pericarditis should be considered in adolescents or young adults with acute chest pain, shortness of breath, or palpitations following recent COVID-19 vaccination. In this younger population, coronary events are less likely to be a source of these symptoms.
- For evaluation of patients with suspected myocarditis or pericarditis:
 - For initial evaluation, consider an ECG, troponin level, and inflammatory markers such as C-reactive protein and erythrocyte sedimentation rate. In the setting of normal ECG, troponin, and inflammatory markers, myocarditis or pericarditis are unlikely.
 - Cardiology consultation is strongly encouraged for assistance with evaluation and management and further testing as indicated to assess the incidence of cardiac injury including echocardiogram and, where appropriate, cMRI.
 - For cases of myocarditis, it is important to evaluate for potential etiologies of myocarditis, particularly acute COVID-19 infection (e.g., PCR testing), prior SARS-CoV-2 infection (i.e., SARS-CoV-2 nucleocapsid antibodies), and other viral etiologies (e.g., enterovirus PCR and comprehensive respiratory viral pathogen testing). Consider consultation with infectious disease for complete evaluation of potential etiologies and/or rheumatology.
- For management of patients with myocarditis or pericarditis:
 - To date, there are no indications to alter management as compared to that of classic myocarditis and pericarditis. Most cases of myocarditis and pericarditis improve with conservative management.
 - For patients with myocarditis, restriction from rigorous athletic activity is recommended for at least 3 months pending repeat evaluation by cardiology.⁴
- CDC continues to recommend [COVID-19 vaccination](#) for individuals 12 years and older.
- Healthcare providers should [report all cases of myocarditis and pericarditis post COVID-19 vaccination to VAERS](#).

Recommendations for Public Health

- Encourage healthcare providers and the public to report myocarditis, pericarditis, and other adverse events following receipt of COVID-19 vaccines to VAERS as required under the [Emergency Use Authorizations for COVID-19 vaccines](#).
- Disseminate this advisory to healthcare providers in your jurisdictions.
- CDC continues to recommend [COVID-19 vaccination](#) for individuals 12 years and older.

Commented [DD(2): Will need to decide what we are calling this communication: Alert, Advisory, etc and then also decided what the recommended circulation should be: pediatrics, adolescent medicine, pediatric emergency medicine, pediatric infectious diseases, and pediatric cardiology?

Recommendations for the Public

- CDC continues to recommend [COVID-19 vaccination](#) for everyone 12 years or older. If you have concerns about vaccination, talk with your or your child's doctor.
- Cases of myocarditis and pericarditis following COVID-19 vaccination are rare and have typically been mild. Also, most patients responded well to everyday treatments, like rest and aspirin or ibuprofen, and quickly felt better. If you or your child received an mRNA COVID-19 vaccine (Pfizer-BioNTech or Moderna) and develops chest pain, shortness of breath, or feelings of having a fast-beating, fluttering, or pounding heart after recent vaccination, contact your doctor, or seek medical care. Avoid rigorous physical activity, such as climbing a steep hill or running, until a doctor has examined you, run any necessary tests, and said you may do those activities again.
- Report possible health problems following receipt of any COVID-19 vaccine to VAERS.

For More Information

- NIH materials on [myocarditis and pericarditis](#)
- Frequently asked questions about VAERS reporting for COVID-19 vaccines [VAERS FAQs \(hhs.gov\)](#)
- How to report to [VAERS](#)

References

1. Sagar S, Liu PP, Cooper LT, Jr. Myocarditis. Lancet. 2012;379:738-47.
2. Ferreira VM, Schulz-Menger J, Holmvang G, Kramer CM, Arborelius J, Schteim U, et al. Cardiovascular Magnetic Resonance in Nonischemic Myocardial Inflammation: Expert Recommendations. J Am Coll Cardiol. 2018;72:3158-7.
3. Adler Y, Charron P, Imazio M, Badano L, Baron-Esquivias G, Bogaert J, et al. 2015 ESC Guidelines for the diagnosis and management of pericardial diseases: The Task Force for the Diagnosis and Management of Pericardial Diseases of the European Society of Cardiology (ESC) Endorsed by: The European Association for Cardio-Thoracic Surgery (EACTS). Eur Heart J. 2015;36:2921-64.
4. Maron BJ, Udelson JE, Bonow RO, Nishimura RA, Ackerman MJ, Estes NAM, 3rd, et al. Eligibility and Disqualification Recommendations for Competitive Athletes With Cardiovascular Abnormalities: Task Force 3: Hypertrophic Cardiomyopathy, Arrhythmogenic Right Ventricular Cardiomyopathy and Other Cardiomyopathies, and Myocarditis: A Scientific Statement From the American Heart Association and American College of Cardiology. J Am Coll Cardiol. 2015;66:2362-71.

From: [Tumpey, Abbigail \(CDC/DDPHSS/CSELS/OD\)](#)
To: [Walensky, Rochelle \(CDC/IOD\)](#); [Schuchat, Anne MD \(CDC/OD\)](#)
Cc: [Goldstein, Robert \(CDC/OD/OADPS\)](#); [Berger, Sherri \(CDC/IOD\)](#); [McDonald, Jason \(CDC/OD/OC\)](#)
Subject: Draft HAN - still in clearance
Date: Wednesday, May 26, 2021 1:49:24 PM
Attachments: [DRAFT Brief Myocarditis HAN 5.25.2021 to JIC - clean.docx](#)

Draft attached. This is still in clearance.

Sharing as preview.

Produced to Homeland Security and Government Affairs Permanent Subcommittee on Investigations Pursuant to Oversight Request
Do Not Disclose Without Permission from U.S. Department of Health and Human Services

Health Alert Network: Cases of Myocarditis and Pericarditis after Receipt of mRNA COVID-19 Vaccines Among Adolescents and Young Adults

Summary

In recent weeks, cases of myocarditis and pericarditis have been reported in the United States after mRNA COVID-19 vaccination (Pfizer-BioNTech or Moderna), particularly in adolescents and young adults. As of May 25, 2021, nearly 25 million doses of COVID-19 vaccine have been administered to individuals between 12-24 years of age, of whom have received 2 doses of mRNA vaccine. As of the same date, CDC has preliminarily identified 155 reports of myocarditis or pericarditis among persons in that age group in the [Vaccine Adverse Event Reporting System \(VAERS\)](#). Of those 155 reports, 92 were among persons who had received the second dose of mRNA vaccine. Many of these reports are under review and are not yet verified. The baseline rate of myocarditis is estimated to be around 1-10 cases/100,000 persons annually in individuals 12-24 years of age, so 8-76 cases of myocarditis would have been expected among the same individuals receiving the second dose of mRNA vaccine over the same period that these cases were reported in VAERS.

Commented [NK(1)]: Still waiting on this data.

In most cases, patients who presented for medical care have responded well to medications and rest, and had favorable outcomes. Reported cases have occurred predominantly in male adolescents and young adults 16 years of age and older. Onset was typically several days to a week after mRNA vaccination, and cases have occurred more often after the second dose than the first dose. CDC and its partners are investigating reports of myocarditis and pericarditis following COVID-19 vaccination to assess for any relationship between the two events.

Commented [NK(2)]: Requested by CDC Director and IM leadership

CDC continues to recommend [COVID-19 vaccination](#) for individuals 12 years and older. The known and potential benefits of COVID-19 vaccination outweigh the known and potential risks, including the possible risk of myocarditis or pericarditis. The purpose of this Health Alert is to ensure that the healthcare provider community is aware of the potential for symptoms with which adolescents and young adults may present after COVID-19 vaccination.

Commented [NK(3)]: Requested by CDC Director, IM, and VTF leadership

Background

Myocarditis is inflammation of the heart muscle, and pericarditis is inflammation of the lining outside the heart. In both cases, the body's immune system is causing inflammation in response to an infection or some other trigger. Symptoms can include palpitations, shortness of breath, or chest pain.

Generally, patients respond to medications and rest but other treatments may be required for more severe cases. Patients can typically return to normal activity after initial improvement in symptoms, though restriction from rigorous activity like competitive sports is typically recommended for at least 3 months for those with myocarditis, due to concerns for sudden cardiac events while the heart recovers.

To date 27,213 adolescents and young adults 12-24 years of age have been hospitalized with COVID-19, 3,742 have been diagnosed with multisystem inflammatory syndrome in children (MIS-C) (age <20), and 1,098 have died due to COVID-19. Vaccination continues to be critical in preventing SARS-CoV-2 transmission, infection, and its severe short- and long-term complications.

Commented [DD(4)]: Requested by IM and Director

Recommendations for Clinicians

- CDC continues to recommend [COVID-19 vaccination](#) for individuals 12 years and older given the greater risk of other serious complications related to COVID-19, such as hospitalization, multisystem inflammatory syndrome in children (MIS-C), or death.
- [Report all cases of myocarditis and pericarditis post COVID-19 vaccination to VAERS.](#)

Commented [NK(5)]: Requested by CDC Director, IM, and VTF leadership

- Consider myocarditis and pericarditis in adolescents or young adults with acute chest pain, shortness of breath, or palpitations. In this younger population, coronary events are less likely to be a source of these symptoms.
 - For initial evaluation, consider an ECG, troponin level, and inflammatory markers such as C-reactive protein and erythrocyte sedimentation rate. In the setting of normal ECG, troponin, and inflammatory markers, myocarditis or pericarditis are unlikely.
- Obtain history of COVID-19 vaccination if you identify these symptoms.
- Provide routine acute care and aftercare for these patients as clinically indicated. Consider restricting patients with myocarditis from rigorous activity like competitive sports for at least 3 months, due to concerns for sudden cardiac events while the heart recovers.
- Consider consultation with cardiology for assistance with evaluation and management of myocarditis and pericarditis.
- Pursue other etiologies of myocarditis and pericarditis and consider consultation with infectious disease and/or rheumatology to assist in this evaluation.
 - Evaluate for potential etiologies of myocarditis and pericarditis, particularly acute COVID-19 infection (e.g., PCR testing), prior SARS-CoV-2 infection (e.g., detection of SARS-CoV-2 nucleocapsid antibodies), and other viral etiologies (e.g., enterovirus PCR and comprehensive respiratory viral pathogen testing). Consider consultation with infectious disease and rheumatology for complete evaluation of potential etiologies.

Recommendations for Public Health

- CDC continues to recommend [COVID-19 vaccination](#) for individuals 12 years and older.
- Encourage healthcare providers and the public to report myocarditis, pericarditis, and other adverse events following receipt of COVID-19 vaccines to VAERS as required under the [Emergency Use Authorizations for COVID-19 vaccines](#).
- Disseminate this alert to healthcare providers in your jurisdictions.

Recommendations for the Public

- CDC continues to recommend [COVID-19 vaccination](#) for everyone 12 years and older. If you have concerns about vaccination, talk with your or your child's doctor.
- The known and potential benefits of COVID-19 vaccination outweigh the known and potential risks, including the possible risk of myocarditis or pericarditis.
- Most patients with myocarditis and pericarditis who have presented to medical care have responded well to medication and rest, and quickly felt better.
- If you or your child received an mRNA COVID-19 vaccine (Pfizer-BioNTech or Moderna) and develop chest pain, shortness of breath, or palpitations (feelings of having a fast-beating, fluttering, or pounding heart) contact your doctor, or seek medical care.
- Report possible health problems following receipt of any COVID-19 vaccine to VAERS.

For More Information

- NIH materials on [myocarditis and pericarditis](#)
- Frequently asked questions about VAERS reporting for COVID-19 vaccines [VAERS – FAQs \(hhs.gov\)](#)
- How to report to [VAERS](#)

From: [Woodcock, Janet](#)
To: [Walensky, Rochelle \(CDC/OD\)](#)
Subject: RE: [EXTERNAL] RE: Rochelle, do you know that FDA does not concur with issuance of the myocarditis HAN as written? jw
Date: Wednesday, May 26, 2021 2:05:22 PM

Thanks so much. I just learned that this was about to go out, despite our concerns. jw

From: Walensky, Rochelle (CDC/OD) <[REDACTED]>
Sent: Wednesday, May 26, 2021 2:00 PM
To: Woodcock, Janet <[REDACTED]>
Subject: [EXTERNAL] RE: Rochelle, do you know that FDA does not concur with issuance of the myocarditis HAN as written? jw

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hi Janet,
Just coming from a hearing and trying to get up to speed. Will hold until we chat.
R

From: Woodcock, Janet <[REDACTED]>
Sent: Wednesday, May 26, 2021 1:52 PM
To: Walensky, Rochelle (CDC/OD) <[REDACTED]>
Subject: Rochelle, do you know that FDA does not concur with issuance of the myocarditis HAN as written? jw

From: [Daskalakis, Demetre \(CDC/DDID/NCHHSTP/DHP\)](#)
To: [Honein, Margaret \(Peggy\) \(CDC/DDID/NCEZID/DPEI\)](#); [Fox, Kimberley \(CDC/DDID/NCIRD/DBD\)](#)
Cc: [Beach, Michael J. \(CDC/DDID/NCEZID/DFWED\)](#); [Christie, Athalia \(CDC/DDPHSIS/CGH/OD\)](#)
Subject: RE: Please read: FDA Email
Date: Thursday, May 27, 2021 4:09:00 PM

I think we are v close!

From: Honein, Margaret (Peggy) (CDC/DDID/NCEZID/DPEI) <[REDACTED]>
Sent: Thursday, May 27, 2021 4:10 PM
To: Daskalakis, Demetre (CDC/DDID/NCHHSTP/DHP) <[REDACTED]> Fox, Kimberley (CDC/DDID/NCIRD/DBD) <[REDACTED]>
Cc: Beach, Michael J. (CDC/DDID/NCEZID/DFWED) <[REDACTED]> Christie, Athalia (CDC/DDPHSIS/CGH/OD) <[REDACTED]>
Subject: RE: Please read: FDA Email

Sounds like good news

thx

Margaret (Peggy) Honein, PhD, MPH
COVID-19 Emergency Response
U.S. Centers for Disease Control and Prevention
[REDACTED]



From: Daskalakis, Demetre (CDC/DDID/NCHHSTP/DHP) <[REDACTED]>
Sent: Thursday, May 27, 2021 4:08 PM
To: Fox, Kimberley (CDC/DDID/NCIRD/DBD) <[REDACTED]> Honein, Margaret (Peggy) (CDC/DDID/NCEZID/DPEI) <[REDACTED]>
Cc: Beach, Michael J. (CDC/DDID/NCEZID/DFWED) <[REDACTED]> Christie, Athalia (CDC/DDPHSIS/CGH/OD) <[REDACTED]>
Subject: RE: Please read: FDA Email

It's going well..

One language change around management and then we can move it forward. I think we are close... they want to walk back this sentence:

- Due to concerns for sudden cardiac events while the heart recovers, consider restricting patients with myocarditis from rigorous activity like competitive sports for at least 3 months until cleared by a healthcare professional.

From: Fox, Kimberley (CDC/DDID/NCIRD/DBD) <[REDACTED]>
Sent: Thursday, May 27, 2021 3:38 PM
To: Honein, Margaret (Peggy) (CDC/DDID/NCEZID/DPEI) <[REDACTED]> Daskalakis, Demetre (CDC/DDID/NCHHSTP/DHP) <[REDACTED]>
Cc: Beach, Michael J. (CDC/DDID/NCEZID/DFWED) <[REDACTED]> Christie, Athalia (CDC/DDPHSIS/CGH/OD) <[REDACTED]>
Subject: RE: Please read: FDA Email

Thanks- Demetre is on a call on this shortly

From: Honein, Margaret (Peggy) (CDC/DDID/NCEZID/DPEI) <[REDACTED]>
Sent: Thursday, May 27, 2021 3:32 PM
To: Daskalakis, Demetre (CDC/DDID/NCHHSTP/DHP) <[REDACTED]> Fox, Kimberley (CDC/DDID/NCIRD/DBD) <[REDACTED]>
Cc: Beach, Michael J. (CDC/DDID/NCEZID/DFWED) <[REDACTED]> Christie, Athalia (CDC/DDPHSIS/CGH/OD) <[REDACTED]>
Subject: FW: Please read: FDA Email

FYI – assume you are looped in

Margaret (Peggy) Honein, PhD, MPH
COVID-19 Emergency Response
U.S. Centers for Disease Control and Prevention
[REDACTED]



From: Holton, Kelly (CDC/DDID/NCIPC/OD) <[REDACTED]>
Sent: Thursday, May 27, 2021 3:07 PM
To: Beach, Michael J. (CDC/DDID/NCEZID/DFWED) <[REDACTED]> Honein, Margaret (Peggy) (CDC/DDID/NCEZID/DPEI) <[REDACTED]> Christie, Athalia (CDC/DDPHSIS/CGH/OD) <[REDACTED]> <akc9@cdc.gov>; Pillai, Satish K. (CDC/DDID/NCEZID/DPEI) <[REDACTED]>
Cc: CDC I.v. JIC Lead -2 <[REDACTED]>
Subject: FW: Please read: FDA Email

All – You may have gotten this through a different channel but forwarding in case you have not seen it. VTF has pulled down the clinical page that went up an hour or so ago and is trying to organize a call with Dr. Marks to discuss concerns.

Kelly

From: Tumpey, Abbigail (CDC/DDPHSS/CELS/OD) <[REDACTED]>

Sent: Thursday, May 27, 2021 2:55 PM

To: Nordlund, Kristen (CDC/DDID/NCIRD/OD) <[REDACTED]> Schindelar, Jessica (CDC/DDID/NCEZID/DHQP) <[REDACTED]> Coffin, Nicole (CDC/DDID/NCEZID/DHQP) <[REDACTED]> Stryker, Jo Ellen (CDC/DDID/NCHHSTP/DHPIRS) <[REDACTED]>

Cc: CDC IMS JIC Lead -2 <[REDACTED]>

Subject: Please read: FDA Email

Calling you all.

From: Walensky, Rochelle (CDC/OD) <[REDACTED]>

Sent: Thursday, May 27, 2021 2:52 PM

To: Tumpey, Abigail (CDC/DDPHSS/CSELS/OD) <[REDACTED]>

Subject: FW: [EXTERNAL] Materials on myocarditis

From: Marks, Peter <[REDACTED]>

Sent: Thursday, May 27, 2021 2:03 PM

To: Walensky, Rochelle (CDC/OD) <[REDACTED]>

Cc: Woodcock, Janet (FDA/CDER) <[REDACTED]>

Subject: RE: [EXTERNAL] Materials on myocarditis

Dear Rochelle,

I need to ask for your patience with me. We still have concerns here if myocarditis and pericarditis have not actually signaled. This is different from the half pager that we spoke about and is pretty close to the original HAN. Can you help me understand why we are doing this when pediatricians and others in the community already seem to be aware?

Happy to jump on a call.

Best Regards,
Peter

From: McNeill, Lorrie <[REDACTED]>

Sent: Thursday, May 27, 2021 10:37 AM

To: Marks, Peter <[REDACTED]>

Subject: FW: [EXTERNAL] Materials on myocarditis

Hi Peter –

These materials just arrived. As noted below, CDC has decided not to issue the HAN and go with the web posting only. Of note, they've modified the web posting from the version we saw on Tuesday to include language on the amount of time until patients should wait to return to competitive sports

(this was in the HAN). I've attached the previous version for comparison (dated 5/25/2021).

Let me know if you'd like me to push back on this.

Thanks –

Lorrie

From: Nordlund, Kristen (CDC/DDID/NCIRD/OD) <[REDACTED]>
Sent: Thursday, May 27, 2021 10:17 AM
To: Cacco, Stephanie <[REDACTED]> McNeill, Lorrie
<[REDACTED]>
Cc: Tumpey, Abigail J (CDC) <[REDACTED]> Hoffman, Katherine T (CDC) <[REDACTED]>
Subject: [EXTERNAL] Materials on myocarditis

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Stephanie and Lorrie,

Thank you for all the help over the last week on this issue. As I mentioned yesterday, we decided to nix the HAN and instead publish clinician considerations (which will go online here: <https://www.cdc.gov/vaccines/covid-19/clinical-considerations/index.html>) and web content for the public and parents (which will go here: <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety.html>). Attached are the near final versions, pending anything from the higher ups.

As mentioned in the reactive/tough QA document, we plan to give a heads up to partners around noon and then post both documents between 2-3. We have an email (through our Clinician Outreach group) going out either late today or Tuesday with links to these resources.

Please let me know if you have any issues/concerns.

Thanks,
Kristen

Kristen Nordlund
CDC Public Affairs

p. [REDACTED] | c. [REDACTED] | e. [REDACTED]

From: [Tumpey, Abbigail \(CDC/DDPHSS/CSELS/OD\)](#)
To: [Walensky, Rochelle \(CDC/OD\)](#)
Cc: [Berger, Sherri \(CDC/OCOO/OD\)](#)
Subject: RE: [EXTERNAL] Materials on myocarditis
Date: Thursday, May 27, 2021 4:06:04 PM

Yes, for about 10 mins, but it was pulled down. Team was under the impression that FDA staff were in agreement with the language. They are regrouping with the SMEs to discuss.

Cc'ing Sherri as FYI.

From: Walensky, Rochelle (CDC/OD) <[REDACTED]>
Sent: Thursday, May 27, 2021 3:24 PM
To: Tumpey, Abbigail (CDC/DDPHSS/CSELS/OD) <[REDACTED]>
Subject: RE: [EXTERNAL] Materials on myocarditis

Thank you – had it already been posted?

R

From: Tumpey, Abbigail (CDC/DDPHSS/CSELS/OD) <aws8@cdc.gov>
Sent: Thursday, May 27, 2021 3:06 PM
To: Walensky, Rochelle (CDC/OD) <[REDACTED]>
Subject: RE: [EXTERNAL] Materials on myocarditis

Rochelle,

Spoke to the team and they are pausing on the clinical considerations language. They are regrouping with the FDA team.

I have asked for Dr. Denise Cardo and others to speak with Dr. Marks and team.

Regards,

Abbigail

From: Walensky, Rochelle (CDC/OD) <[REDACTED]>
Sent: Thursday, May 27, 2021 2:52 PM
To: Tumpey, Abbigail (CDC/DDPHSS/CSELS/OD) <[REDACTED]>
Subject: FW: [EXTERNAL] Materials on myocarditis

From: Marks, Peter <[REDACTED]>
Sent: Thursday, May 27, 2021 2:03 PM
To: Walensky, Rochelle (CDC/OD) <[REDACTED]>

Cc: Woodcock, Janet (FDA/CDER) <[REDACTED]>
Subject: RE: [EXTERNAL] Materials on myocarditis

Dear Rochelle,

I need to ask for your patience with me. We still have concerns here if myocarditis and pericarditis have not actually signaled. This is different from the half pager that we spoke about and is pretty close to the original HAN. Can you help me understand why we are doing this when pediatricians and others in the community already seem to be aware?

Happy to jump on a call.

Best Regards,
Peter

From: McNeill, Lorrie <[REDACTED]>
Sent: Thursday, May 27, 2021 10:37 AM
To: Marks, Peter <[REDACTED]>
Subject: FW: [EXTERNAL] Materials on myocarditis

Hi Peter –

These materials just arrived. As noted below, CDC has decided not to issue the HAN and go with the web posting only. Of note, they've modified the web posting from the version we saw on Tuesday to include language on the amount of time until patients should wait to return to competitive sports (this was in the HAN). I've attached the previous version for comparison (dated 5/25/2021).

Let me know if you'd like me to pick up on this.

Thanks –

Lorrie

From: Nordlund, Kristen (CDC/DDID/NCIRD/OD) <[REDACTED]>
Sent: Thursday, May 27, 2021 10:17 AM
To: Caccamo, Stephanie <[REDACTED]> McNeill, Lorrie
[REDACTED]
Cc: Tumpey, Abigail J (CDC) <[REDACTED]> Hoffman, Katherine T (CDC) <[REDACTED]>
Subject: [EXTERNAL] Materials on myocarditis

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Stephanie and Lorrie,

Thank you for all the help over the last week on this issue. As I mentioned yesterday, we decided to nix the HAN and instead publish clinician considerations (which will go online here: <https://www.cdc.gov/vaccines/covid-19/clinical-considerations/index.html>) and web content for the public and parents (which will go here: <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety.html>). Attached are the near final versions, pending anything from the higher ups.

As mentioned in the reactive/tough QA document, we plan to give a heads up to partners around noon and then post both documents between 2-3. We have an email (through our Clinician Outreach group) going out either late today or Tuesday with links to these resources.

Please let me know if you have any issues/concerns.

Thanks,
Kristen

Kristen Nordlund
CDC Public Affairs

p. [REDACTED] | c. [REDACTED] | e. [REDACTED]

Produced to Homeland Security and Government Affairs Permanent Subcommittee on Investigations Pursuant to Oversight Request
Do Not Disclose Without Permission from U.S. Department of Health and Human Services

**Primary Domestic VAERS COVID-19 Reports by Jurisdiction and Severity
Vaccinated and Received: December 14, 2020 - 04/01/2022 or missing
VAERS reports as of 04/01/2022 at 3PM
(N=803841)**

1

Jurisdiction	Estimated Population ^{1,2}	Death Reports ⁴ N(%)	Non-Death Serious Reports ⁵ N(%)	Non-Serious Reports N(%)	All Reports N
Alaska	731,545	33 (1.4)	101 (4.3)	2,234 (94.3)	2368
Alabama	4,903,185	84 (1.2)	418 (5.9)	6,605 (92.9)	7107
Arkansas	3,017,804	105 (2.2)	578 (12.2)	4,052 (85.6)	4735
Arizona	7,278,717	135 (0.8)	1,008 (6.0)	15,574 (93.2)	16717
California	39,512,223	642 (0.8)	4,763 (6.2)	71,668 (93.0)	77073
Colorado	5,758,736	116 (0.8)	1,175 (8.1)	13,280 (91.1)	14571
Connecticut	3,565,287	68 (0.7)	633 (6.1)	9,597 (93.2)	10298
District of Columbia	705,749	18 (0.9)	116 (5.8)	1,865 (93.3)	1999
Delaware	973,764	22 (1.0)	161 (7.4)	2,004 (91.6)	2187
Florida	21,477,737	518 (1.2)	4,216 (9.5)	39,784 (89.4)	44518
Georgia	10,617,423	342 (1.9)	1,426 (7.7)	16,639 (90.4)	18407
Hawaii	1,415,872	41 (1.4)	202 (6.7)	2,766 (91.9)	3009
Iowa	3,155,070	102 (1.7)	562 (9.5)	5,278 (88.8)	5942
Idaho	1,787,065	29 (0.8)	235 (6.8)	3,215 (92.4)	3479
Illinois	12,671,821	338 (1.3)	2,156 (8.5)	22,726 (90.1)	25220
Indiana	6,732,219	158 (0.6)	822 (3.1)	25,612 (96.3)	26592
Kansas	2,913,314	81 (1.4)	398 (6.9)	5,296 (91.7)	5775
Kentucky	4,467,673	735 (6.3)	1,882 (16.2)	9,015 (77.5)	11632
Louisiana	4,648,794	77 (1.2)	427 (6.7)	5,837 (92.1)	6341
Massachusetts	6,892,503	147 (0.8)	1,265 (7.0)	16,588 (92.2)	18000
Maryland	6,045,680	136 (0.9)	1,197 (7.8)	13,961 (91.3)	15294
Maine	1,344,212	39 (1.0)	237 (6.0)	3,645 (93.0)	3921
Michigan	9,986,857	641 (2.4)	5,820 (21.5)	20,640 (76.2)	27101
Minnesota	5,639,632	450 (2.5)	3,306 (18.5)	14,068 (78.9)	17824
Missouri	6,137,428	257 (2.1)	1,219 (9.8)	10,949 (88.1)	12425

¹ Source for Estimated State Data: <https://www.census.gov/data/tables/time-series/demo/popest/2010s-state-total.html>

² Source for 2018 Estimated Freely Associated States and Guam Data: <https://sdd.spc.int/>

³ Source for 2020 Estimated US Virgin Islands Data: <https://www.worldometers.info/world-population/united-states-virgin-islands-population/>

⁴ Death Reports include unconfirmed reports of death. Some cases are pending confirmation by autopsy, medical record, or death certificate (VAERS form Item 21)

⁵ Non-Death Serious reports include reports of life-threatening conditions, hospitalization, extended hospitalization, permanent disability, or birth defect (VAERS form Item 21)

**Primary Domestic VAERS COVID-19 Reports by Jurisdiction and Severity
Vaccinated and Received: December 14, 2020 - 04/01/2022 or missing
VAERS reports as of 04/01/2022 at 3PM
(N=803841)**

Jurisdiction	Estimated Population^{1,2}	Death Reports⁴ N(%)	Non-Death Serious Reports⁵ N(%)	Non-Serious Reports N(%)	All Reports N
Mississippi	2,976,149	64 (1.9)	198 (5.7)	3,188 (92.4)	3450
Montana	1,068,778	112 (3.5)	517 (16.4)	2,532 (80.1)	3161
North Carolina	10,488,084	168 (0.8)	1,456 (7.3)	18,188 (91.8)	19812
North Dakota	762,062	39 (2.4)	286 (17.3)	1,330 (80.4)	1655
Nebraska	1,934,408	58 (1.6)	279 (7.8)	3,235 (90.6)	3572
New Hampshire	1,359,711	84 (2.1)	287 (7.3)	3,544 (90.5)	3915
New Jersey	8,882,190	199 (0.9)	1,738 (7.6)	21,060 (91.6)	22997
New Mexico	2,096,829	51 (1.1)	235 (5.1)	4,323 (93.8)	4609
Nevada	3,080,156	44 (0.8)	428 (8.1)	4,818 (91.1)	5290
New York	19,453,561	376 (0.9)	3,042 (7.1)	39,287 (92.0)	42705
Ohio	11,689,100	328 (1.4)	2,030 (8.7)	20,916 (89.9)	23274
Oklahoma	3,956,971	138 (1.8)	603 (7.8)	7,038 (90.5)	7779
Oregon	4,217,737	83 (0.8)	738 (7.0)	9,775 (92.3)	10596
Pennsylvania	12,801,989	281 (1.0)	2,028 (7.2)	25,754 (91.8)	28063
Rhode Island	1,059,361	21 (0.8)	162 (6.3)	2,381 (92.9)	2564
South Carolina	5,148,714	74 (0.9)	560 (7.0)	7,384 (92.1)	8018
South Dakota	884,659	130 (8.0)	107 (6.6)	1,391 (85.4)	1628
Tennessee	6,829,174	811 (6.7)	949 (7.9)	10,329 (85.4)	12089
Texas	28,995,881	724 (1.6)	2,844 (6.4)	40,736 (91.9)	44304
Utah	3,205,958	38 (0.7)	350 (6.4)	5,057 (92.9)	5445
Virginia	8,535,519	158 (0.9)	1,260 (6.9)	16,927 (92.3)	18345
Vermont	623,989	15 (0.7)	108 (5.2)	1,944 (94.0)	2067
Washington	7,614,893	210 (1.1)	1,466 (7.7)	17,314 (91.2)	18990
Wisconsin	5,822,434	403 (2.9)	1,378 (9.8)	12,311 (87.4)	14092
West Virginia	1,792,147	67 (2.2)	286 (9.5)	2,671 (88.3)	3024

¹ Source for Estimated State Data: <https://www.census.gov/data/tables/time-series/demo/popest/2010s-state-total.html>

² Source for 2018 Estimated Freely Associated States and Guam Data: <https://sdd.spc.int/>

³ Source for 2020 Estimated US Virgin Islands Data: <https://www.worldometers.info/world-population/united-states-virgin-islands-population/>

⁴ Death Reports include unconfirmed reports of death. Some cases are pending confirmation by autopsy, medical record, or death certificate (VAERS form Item 21)

⁵ Non-Death Serious reports include reports of life-threatening conditions, hospitalization, extended hospitalization, permanent disability, or birth defect (VAERS form Item 21)

Primary Domestic VAERS COVID-19 Reports by Jurisdiction and Severity
Vaccinated and Received: December 14, 2020 - 04/01/2022 or missing
VAERS reports as of 04/01/2022 at 3PM
(N=803841)

Jurisdiction	Estimated Population^{1,2}	Death Reports⁴ N(%)	Non-Death Serious Reports⁵ N(%)	Non-Serious Reports N(%)	All Reports N
Wyoming	578,759	24 (2.4)	77 (7.8)	891 (89.8)	992
Not Specified	NA	2,696 (2.6)	9,676 (9.3)	91,787 (88.1)	104159
United States	328,239,523	12,710 (1.6)	67,411 (8.4)	719,009 (90.0)	799130
American Samoa	56,700	1 (2.9)	1 (2.9)	32 (94.1)	34
Federated States of Micronesia	105,300		2 (40.0)	3 (60.0)	5
Guam	172,400	4 (2.5)	14 (8.6)	145 (89.0)	163
Republic of the Marshall Islands	55,500		1 (16.7)	5 (83.3)	6
Commonwealth of the Northern Mariana Islands	56,200	11 (28.9)	5 (13.2)	22 (57.9)	38
Puerto Rico	3,193,694	118 (2.7)	157 (3.6)	4,089 (93.7)	4364
Republic of Palau	17,900			2 (100.0)	2
QM	NA			2 (100.0)	2
Tx	NA			1 (100.0)	1
U.S. Virgin Islands	104,433		5 (5.4)	87 (94.6)	92
XB	NA		1 (50.0)	1 (50.0)	2
XV	NA		1 (50.0)	1 (50.0)	2

¹ Source for Estimated State Data: <https://www.census.gov/data/tables/time-series/demo/popest/2010s-state-total.html>

² Source for 2018 Estimated Freely Associated States and Guam Data: <https://sdd.spc.int/>

³ Source for 2020 Estimated US Virgin Islands Data: <https://www.worldometers.info/world-population/united-states-virgin-islands-population/>

⁴ Death Reports include unconfirmed reports of death. Some cases are pending confirmation by autopsy, medical record, or death certificate (VAERS form Item 21)

⁵ Non-Death Serious reports include reports of life-threatening conditions, hospitalization, extended hospitalization, permanent disability, or birth defect (VAERS form Item 21)

PREFERRED Medical Dictionary for Regulatory Activities (MedDRA) Terms (VAERS-1 Box 7, VAERS 2.0 Box 18)

For Current Week and Past Week Comparison

Following **ALL 12/14/2020-04/01/2022 COVID19 MODERNA Ages 18+ Vaccines**

Compared to **ALL 12/14/2020-04/01/2022 COVID19 PFIZER Ages 18+ Vaccines**

AGES 18+ YEARS, Initial domestic reports only, VAERS reports as of 04/01/2022

Vaccination, Received, and Completed Date: 12/14 - 04/01 (Current Week) and 12/14 - 03/25 (Past Week)

N>=3 (Current Week), PRR>=2.00 (Ratio of Proportions), Chi-Square>=4.00

MedDRA PTs sorting based on lower confidence limit and MODERNA adverse event count from 12/14/2020-04/01/2022

AGES 18+ YEARS excludes missing ages

MedDRA Codes ALL Reports (18+)	12/14/2020- 04/01/2022 MODERNA N=321994	12/14/2020- 04/01/2022 PFIZER N=301241	12/14-04/01 Chi-Square	12/14-04/01 PRR	12/14-04/01 LCL	12/14-04/01 UCL	12/14/2020- 03/25/2022 MODERNA N=320915	12/14/2020- 03/25/2022 PFIZER N=299926	12/14-03/25 Chi-Square	12/14-03/25 PRR	12/14-03/25 LCL	12/14-03/25 UCL
PRODUCT DOSE OMISSION ISSUE	1627	68	1335.30	22.38	17.56	28.53	1627	67	1336.45	22.70	17.78	28.98
MECHANICAL URTICARIA	738	54	545.69	12.79	9.70	16.85	727	52	539.76	13.07	9.86	17.31
VACCINATION SITE INDURATION	1083	100	753.33	10.13	8.26	12.43	1083	100	752.40	10.12	8.25	12.42
ACCIDENTAL OVERDOSE	264	19	194.74	13.00	8.16	20.71	260	19	190.85	12.79	8.03	20.38
INTENTIONAL PRODUCT USE ISSUE	132	9	97.72	13.72	6.98	26.95	132	9	97.61	13.71	6.98	26.93
INJECTION SITE RASH	10238	1383	6293.26	6.93	6.55	7.32	10239	1384	6283.99	6.91	6.54	7.31
INJECTION SITE PRURITUS	18131	2576	11049.40	6.58	6.32	6.86	18130	2575	11036.72	6.58	6.32	6.86
INJECTION SITE INDURATION	5063	726	2996.47	6.52	6.04	7.05	5058	726	2988.00	6.51	6.02	7.04
INJECTION SITE WARMTH	13096	2083	7462.21	5.88	5.62	6.16	13096	2078	7461.96	5.89	5.63	6.17
DEVICE CONNECTION ISSUE	301	42	177.56	6.70	4.86	9.26	300	42	176.44	6.68	4.83	9.22
INJECTION SITE ERYTHEMA	25281	4734	13388.10	5.00	4.85	5.15	25285	4730	13381.22	5.00	4.85	5.15
TYPE IV HYPERSENSITIVITY REACTION	117	13	74.99	8.42	4.75	14.93	117	13	74.89	8.41	4.74	14.92
INTENTIONAL DOSE OMISSION	83	9	53.23	8.63	4.34	17.16	83	9	53.16	8.62	4.33	17.15
PRODUCT LABEL CONFUSION	44	3	31.47	13.72	4.26	44.19	44	3	31.43	13.71	4.26	44.14
VACCINATION SITE WARMTH	2711	553	1293.61	4.59	4.19	5.02	2709	553	1289.94	4.58	4.18	5.02
VACCINATION SITE PRURITUS	3262	675	1542.19	4.52	4.16	4.91	3261	673	1542.31	4.53	4.17	4.92
INJECTION SITE HYPERSENSITIVITY	151	22	86.49	6.42	4.11	10.04	151	22	86.37	6.41	4.10	10.03
INJECTION SITE REACTION	4023	868	1844.95	4.33	4.03	4.66	4023	864	1849.43	4.35	4.04	4.68
VACCINATION SITE RASH	2064	433	963.17	4.46	4.02	4.95	2064	432	963.31	4.47	4.03	4.95
VACCINATION SITE REACTION	1043	210	499.99	4.65	4.01	5.39	1043	210	499.21	4.64	4.00	5.38
INJECTION SITE URTICARIA	1276	263	601.92	4.54	3.98	5.18	1275	263	600.15	4.53	3.97	5.17
INJECTION SITE INFLAMMATION	872	179	411.86	4.56	3.88	5.35	872	179	411.20	4.55	3.88	5.35
POOR QUALITY PRODUCT ADMINISTERED	790	163	371.55	4.53	3.83	5.37	789	156	382.04	4.73	3.98	5.61
INJECTION SITE SWELLING	19600	4865	8252.13	3.77	3.65	3.89	19600	4857	8251.35	3.77	3.66	3.89
VACCINATION SITE LYMPHADENOPATHY	153	26	80.61	5.51	3.63	8.34	153	26	80.49	5.50	3.63	8.33
INDURATION	1714	405	725.90	3.96	3.55	4.41	1712	405	723.09	3.95	3.55	4.40
INJECTION SITE PAPULE	53	6	32.91	8.26	3.55	19.22	53	6	32.86	8.26	3.55	19.20
INJECTION SITE CELLULITIS	330	69	152.82	4.47	3.45	5.80	331	69	153.39	4.48	3.46	5.81
EXPIRED PRODUCT ADMINISTERED	11244	2934	4437.60	3.59	3.44	3.73	11182	2906	4422.45	3.60	3.45	3.74
VACCINATION SITE ERYTHEMA	4865	1258	1911.18	3.62	3.40	3.85	4861	1256	1907.66	3.62	3.40	3.85
INJECTION SITE IRRITATION	258	53	120.77	4.55	3.39	6.12	258	53	120.57	4.55	3.39	6.11
PRODUCT ADMINISTRATION INTERRUPTED	31	3	19.70	9.67	2.96	31.62	31	3	19.68	9.66	2.95	31.59
INJECTION SITE MASS	2305	679	784.64	3.18	2.92	3.46	2302	679	780.92	3.17	2.91	3.45

LOCAL REACTION	233	56	95.93	3.89	2.91	5.21	233	55	97.30	3.96	2.95	5.31
SKIN WARM	6797	2181	2107.54	2.92	2.78	3.06	6801	2179	2108.61	2.92	2.78	3.06
VACCINATION SITE URTICARIA	252	66	95.81	3.57	2.72	4.68		66	95.64	3.57	2.72	4.68
INJECTION SITE NODULE	897	271	294.99	3.10	2.70	3.55	895	268	296.85	3.12	2.72	3.58
VACCINATION COMPLICATION	2662	888	776.64	2.80	2.60	3.03	2663	888	775.88	2.80	2.60	3.02
SKIN INDURATION	160	41	61.73	3.65	2.59	5.14	160	40	63.08	3.74	2.64	5.29
SKIN REACTION	550	168	178.00	3.06	2.58	3.64	549	167	178.20	3.07	2.58	3.65
MATERNAL EXPOSURE DURING PREGNANCY	719	227	223.78	2.96	2.55	3.44	718	225	225.11	2.98	2.57	3.46
VACCINATION SITE DISCOLOURATION	258	73	90.55	3.31	2.55	4.29	257	73	89.64	3.29	2.54	4.27
INJECTION SITE OEDEMA	173	47	63.03	3.44	2.49	4.75	171	47	61.42	3.40	2.46	4.70
VACCINATION SITE MOVEMENT IMPAIRMENT	264	79	86.98	3.13	2.43	4.02	264	79	86.80	3.12	2.43	4.02
INJECTION SITE INDENTATION	100	25	39.07	3.74	2.41	5.80	100	25	39.00	3.74	2.41	5.79
VACCINATION SITE SWELLING	3746	1418	907.87	2.47	2.33	2.63	3740	1416	903.97	2.47	2.32	2.62
POST-ACUTE COVID-19 SYNDROME	228	70	72.70	3.05	2.33	3.98	228	68	75.12	3.13	2.39	4.11
INJECTION SITE DISCOLOURATION	468	159	131.76	2.75	2.30	3.30	466	159	130.12	2.74	2.29	3.28
CELLULITIS	1174	438	289.03	2.51	2.25	2.80	1174	433	293.66	2.53	2.27	2.83
VACCINATION SITE DISCHARGE	41	8	18.84	4.79	2.25	10.23	41	8	18.81	4.79	2.25	10.22
RASH PRYTHEMATOUS	7382	3025	1512.05	2.25	2.16	2.35	7280	3015	1516.38	2.26	2.16	2.35
CHRONIC SPONTANEOUS URTICARIA	108	32	35.39	3.16	2.13	4.68	105	31	34.45	3.17	2.12	4.73
PRODUCT AVAILABILITY ISSUE	26	4	13.35	6.08	2.12	17.42	26	4	13.33	6.07	2.12	17.41
INJECTION SITE STREAKING	47	11	18.88	4.00	2.07	7.71	47	11	18.84	3.99	2.07	7.70
EXPOSURE VIA SKIN CONTACT	119	38	35.66	2.93	2.03	4.22	119	38	35.58	2.93	2.03	4.22
ERYTHEMA	15815	7129	2842.25	2.08	2.02	2.13	15793	7106	2841.56	2.08	2.02	2.14
EXPOSURE VIA BREAST MILK	54	14	19.87	3.61	2.00	6.50	54	14	19.83	3.60	2.00	6.49
SKIN SWELLING	487	197	103.85	2.31	1.96	2.73	484	195	103.69	2.32	1.96	2.74
INJECTION SITE ABSCESS	81	25	25.02	3.03	1.94	4.75	81	25	24.97	3.03	1.93	4.74
INJECTION SITE INFECTION	106	35	30.29	2.83	1.93	4.15	106	35	30.22	2.83	1.93	4.15
VACCINATION SITE CELLULITIS	45	13	14.59	3.24	1.75	6.00	45	13	14.56	3.24	1.75	6.00
ERYTHEMA MCLIFORME	128	50	28.42	2.40	1.73	3.32	127	50	27.74	2.37	1.71	3.29
VACCINATION SITE INFLAMMATION	159	65	32.71	2.29	1.71	3.05	159	65	32.63	2.29	1.71	3.05
ANTIBODY TEST NEGATIVE	24	5	10.03	4.49	1.71	11.77	24	5	10.00	4.49	1.71	11.76
SKIN INFECTION	66	24	16.07	2.57	1.61	4.10	67	23	17.76	2.72	1.70	4.37
INJECTION SITE MACULE	22	5	8.46	4.12	1.56	10.87	22	5	8.44	4.11	1.56	10.86
INJECTION SITE EXTRAVASATION	91	38	17.66	2.24	1.53	3.27	91	38	17.62	2.24	1.53	3.27
URTICARIA CHRONIC	113	50	19.66	2.11	1.52	2.95	109	50	17.44	2.04	1.46	3.85
INJECTION SITE PUSTULE	37	12	10.22	2.88	1.50	5.53	37	12	10.20	2.88	1.50	5.53
TOOTH LOSS	21	5	7.69	3.93	1.48	10.42	21	5	7.68	3.93	1.48	10.41
INJECTION SITE LYMPHADENOPATHY	84	37	14.58	2.12	1.44	3.13	84	37	14.54	2.12	1.44	3.12
VACCINATION SITE SCAR	25	8	6.74	2.92	1.32	6.48	25	7	7.93	3.34	1.44	7.72
INJECTION SITE SCAR	56	25	9.21	2.10	1.31	3.36	56	25	9.19	2.09	1.31	3.35
INJECTION SITE SCAR	36	14	7.49	2.41	1.30	4.46	36	14	7.47	2.40	1.30	4.46
MULTIPLE USE OF SINGLE USE PRODUCT	14	3	5.24	4.37	1.25	15.19	14	3	5.23	4.36	1.25	15.18
MYOCLEROSIS	38	16	6.84	2.22	1.24	3.98	38	16	6.82	2.22	1.24	3.98
LIMB IMMOBILISATION	32	13	6.06	2.30	1.21	4.39	32	13	6.04	2.30	1.21	4.38
DENTAL DISCOMFORT	37	16	6.38	2.16	1.20	3.89	37	16	6.26	2.16	1.20	3.88
FEELING OF RELAXATION	26	10	5.30	2.43	1.17	5.04	26	10	5.28	2.43	1.17	5.04

PRODUCT COLOUR ISSUE	13	3	4.49	4.05	1.16	14.23	13	3	4.48	4.05	1.15	14.21
INJECTION RELATED REACTION	20	7	4.57	2.67	1.13	6.32	20	6	5.66	3.12	1.25	7.76
LEFT VENTRICULAR ENLARGEMENT	18	6	4.34	2.81	1.11	7.07	18	6	4.33	2.80	1.11	7.06
GINGIVITIS	21	8	4.20	2.46	1.09	5.54	21	8	4.19	2.45	1.09	5.54
ACCIDENTAL UNDERDOSE	197	2	176.68	92.15	22.89	371.05	193	2	172.76	90.19	22.40	363.20
ANAESTHESIA	19	1	13.36	17.78	2.38	132.78	19	1	13.34	17.76	2.38	132.64
VACCINATION SITE	19	1	13.36	17.78	2.38	132.78	19	1	13.34	17.76	2.38	132.64
DYSAESTHESIA	16	2	8.55	7.48	1.72	32.55	16	2	8.54	7.48	1.72	32.52
VACCINATION SITE	13	2	6.02	6.08	1.37	26.95	13	2	6.01	6.07	1.37	26.92
HYPERSENSITIVITY	11	2	4.41	5.15	1.14	23.21	11	2	4.40	5.14	1.14	23.19
PRODUCT EXPIRATION DATE	9	1	4.45	8.42	1.07	66.46	9	1	4.44	8.41	1.07	66.39
VACCINATION SITE STREAKING	19	1	13.36	17.78	2.38	132.78	19	1	13.31	17.76	2.38	132.64
PULMONARY HILUM MASS												
PRODUCT CONTAMINATION												
PHYSICAL												

PREFERRED Medical Dictionary for Regulatory Activities (MedDRA) Terms (VAERS-1 Box 7, VAERS 2.0 Box 18)

For Current Week and Past Week Comparison

Following **ALL 12/14/2020-04/01/2022 COVID19 MODERNA Ages 18+ Vaccines**

Compared to **ALL 12/14/2020-04/01/2022 COVID19 PFIZER Ages 18+ Vaccines**

SERIOUS AGES 18+ YEARS, Initial domestic reports only, VAERS reports as of 04/01/2022

Vaccination, Received, and Completed Date: 12/14 - 04/01 (Current Week) and 12/14 - 03/25 (Past Week)

N₁≥3 (Current Week), PRR₁≥2.00 (Ratio of Proportions), Chi-Square₁≥4.00

MedDRA PTs sorting based on lower confidence limit and MODERNA adverse event count from 12/14/2020-04/01/2022

SERIOUS AGES 18+ YEARS excludes missing ages

MedDRA Codes ALL Reports (SERIOUS 18+)	12/14/2020- 04/01/2022 MODERNA N=29626	12/14/2020- 04/01/2022 PFIZER N=36199	12/14-04/01 Chi-Square	12/14-04/01 PRR	12/14-04/01 LCL	12/14-04/01 UCL	12/14/2020- 03/25/2022 MODERNA N=29263	12/14/2020- 03/25/2022 PFIZER N=35833	12/14-03/25 Chi-Square	12/14-03/25 PRR	12/14-03/25 LCL	12/14-03/25 UCL
PRODUCT DOSE OMISSION	127	18	104.73	8.62	5.26	14.12	127	17	107.30	9.15	5.52	15.17
ISSUE												
MECHANICAL URTICARIA	20	3	14.71	8.15	2.42	27.41	20	3	14.75	8.16	2.43	27.47
INJECTION SITE ERYTHEMA	132	54	49.74	2.99	2.18	4.10	132	54	49.96	2.99	2.18	4.11
VACCINATION SITE ERYTHEMA	35	12	15.32	3.56	1.85	6.86	35	12	15.39	3.57	1.85	6.88
INJECTION SITE PRURITUS	62	28	19.81	2.71	1.73	4.23	62	27	21.00	2.81	1.79	4.42
INJECTION SITE SWELLING	138	75	32.99	2.25	1.70	2.98	138	75	33.18	2.25	1.70	2.98
INJECTION SITE REACTION	46	21	14.21	2.68	1.60	4.48	46	20	15.36	2.82	1.67	4.76
INCOMPLETE COURSE OF VACCINATION	99	57	20.78	2.12	1.53	2.94	99	57	20.90	2.13	1.54	2.95
INJECTION SITE WARMTH	52	26	13.94	2.44	1.53	3.91	52	26	14.01	2.45	1.53	3.92
DRUG REACTION WITH EOSINOPHILIA AND SYSTEMIC SYMPTOMS	17	5	8.00	4.15	1.53	11.26	17	5	8.03	4.16	1.54	11.28
OPTIC ISCHAEMIC NEUROPATHY	20	7	8.08	3.49	1.48	8.25	20	7	8.12	3.50	1.48	8.27
VACCINATION SITE RASH	14	4	6.54	4.28	1.41	12.99	14	4	6.57	4.29	1.41	13.02
VACCINATION SITE REACTION	14	4	6.54	4.28	1.41	12.99	14	4	6.57	4.29	1.41	13.02
VENA CAVA THROMBOSIS	12	3	6.08	4.89	1.38	17.32	12	3	6.10	4.90	1.38	17.36
VACCINATION SITE WARMTH	17	6	6.64	3.46	1.37	8.78	17	6	6.67	3.47	1.37	8.80
SUDDEN CARDIAC DEATH	42	23	9.33	2.23	1.34	3.71	41	23	8.70	2.18	1.31	3.64
RASH PAPULAR	40	22	8.77	2.22	1.32	3.74	40	22	8.82	2.23	1.32	3.74
CHOLECYSTITIS INFECTIVE	16	6	5.76	3.26	1.28	8.33	16	6	5.78	3.27	1.28	8.34
CARDIAC DISCOMFORT	21	10	5.59	2.57	1.21	5.45	21	11	4.72	2.34	1.13	4.85
INJECTION SITE INDURATION	25	13	5.82	2.35	1.20	4.59	25	13	5.85	2.35	1.20	4.60
FACET JOINT SYNDROME	15	6	4.91	3.05	1.19	7.87	15	6	4.93	3.06	1.19	7.89
DISSOCIATION	12	4	4.67	3.67	1.18	11.36	12	4	4.69	3.67	1.18	11.39
GRANULOMA	12	4	4.67	3.67	1.18	11.36	12	4	4.69	3.67	1.18	11.39
LEFT VENTRICULAR ENLARGEMENT	12	4	4.67	3.67	1.18	11.36	12	4	4.69	3.67	1.18	11.39
BRAIN STEM INFARCTION	26	15	4.90	2.12	1.12	4.00	26	15	4.93	2.12	1.12	4.01
TOBACCO USER	26	15	4.90	2.12	1.12	4.00	26	15	4.93	2.12	1.12	4.01
NERVE BLOCK	10	3	4.14	4.07	1.12	14.80	10	3	4.16	4.08	1.12	14.83
IMPAIRED HEALING	22	12	4.57	2.24	1.11	4.53	22	12	4.59	2.24	1.11	4.54
ECTOPIC PREGNANCY	10	3	4.14	4.07	1.12	14.80	9	2	4.64	5.51	1.19	25.50
SLEEP DEFICIT	13	2	8.90	7.94	1.79	35.19	13	2	8.93	7.96	1.80	35.27
VACCINATION SITE INDURATION	12	2	7.80	7.33	1.64	32.75	12	2	7.83	7.35	1.64	32.82
INTENTIONAL DOSE OMISSION	11	2	6.72	6.72	1.49	30.32	11	2	6.74	6.73	1.49	30.38
PULMONARY HILUM MASS	9	1	6.46	11.00	1.39	86.79	9	1	6.48	11.02	1.40	86.98
FOOT DEFORMITY	10	2	5.66	6.11	1.34	27.88	10	2	5.68	6.12	1.34	27.94
HYPERAMMONAEMIA	8	1	5.34	9.77	1.22	78.15	8	1	5.36	9.80	1.23	78.32

CONNECTIVE TISSUE DISORDER	9	2	4.63	5.50	1.19	25.45	9	2	4.64	5.51	1.19	25.50
SCHIZOPHRENIA	9	2	4.63	5.50	1.19	25.45	9	2	4.64	5.51	1.19	25.50
CHRONIC SPONTANEOUS URTICARIA	9	2	4.63	5.50	1.19	25.45	8	2	3.65	4.90	1.04	23.06
EMBOLISM VENOUS	24	15	3.67	1.95	1.03	3.73	24	13	5.15	2.26	1.15	4.44
HALLUCINATION, VISUAL	25	16	3.61	1.91	1.02	3.58	25	15	4.30	2.04	1.08	3.87

PREFERRED Medical Dictionary for Regulatory Activities (MedDRA) Terms (VAERS-1 Box 7, VAERS 2.0 Box 18)

For Current Week and Past Week Comparison

Following **ALL 12/14/2020-04/01/2022 COVID19 MODERNA Ages 18+ Vaccines**Compared to **ALL 12/14/2020-04/01/2022 COVID19 PFIZER Ages 18+ Vaccines****NON-SERIOUS AGES 18+ YEARS**, Initial domestic reports only, VAERS reports as of 04/01/2022

Vaccination, Received, and Completed Date: 12/14 - 04/01 (Current Week) and 12/14 - 03/25 (Past Week)

N $\geq$ 3 (Current Week), PRR $\geq$ 2.00 (Ratio of Proportions), Chi-Square $\geq$ 4.00

MedDRA PTs sorting based on lower confidence limit and MODERNA adverse event count from 12/14/2020-04/01/2022

NON-SERIOUS AGES 18+ YEARS excludes missing ages

MedDRA Codes ALL Reports (NON-SERIOUS 18+)	12/14/2020- 04/01/2022 MODERNA N=292368	12/14/2020- 04/01/2022 PFIZER N=265042	12/14-04/01 Chi-Square	12/14-04/01 PRR	12/14-04/01 LCL	12/14-04/01 UCL	12/14/2020- 03/25/2022 MODERNA N=291652	12/14/2020- 03/25/2022 PFIZER N=264093	12/14-03/25 Chi-Square	12/14-03/25 PRR	12/14-03/25 LCL	12/14-03/25 UCL
PRODUCT DOSE OMISSION												
ISSUE	1500	50	1222.57	27.20	20.52	36.05	1500	50	1221.08	27.17	20.50	36.00
ACCIDENTAL OVERDOSE	257	12	198.62	19.41	10.88	34.64	253	12	194.78	19.09	10.70	34.06
MECHANICAL URTICARIA	718	51	515.29	12.76	9.61	16.95	707	49	509.61	13.07	9.78	17.45
VACCINATION SITE												
INDURATION	1071	98	718.94	9.91	8.06	12.18	1071	98	717.94	9.90	8.05	12.17
INJECTION SITE RASH	10188	1349	6071.56	6.85	6.47	7.24	10189	1350	6061.53	6.83	6.46	7.23
INTENTIONAL PRODUCT USE												
ISSUE	124	9	87.09	12.49	6.35	24.57	124	9	86.97	12.48	6.34	24.54
INJECTION SITE PRURITUS	18069	2548	10628.69	6.43	6.17	6.70	18068	2548	10612.51	6.42	6.16	6.69
INJECTION SITE INDURATION	5038	713	2877.48	6.41	5.92	6.93	5033	713	2868.81	6.39	5.91	6.91
INJECTION SITE WARMTH	13044	2057	7162.27	5.75	5.49	6.02	13044	2052	7160.96	5.76	5.50	6.03
TYPE IV HYPERSENSITIVITY												
REACTION	116	11	75.47	9.56	5.15	17.74	116	11	75.37	9.55	5.15	17.72
DEVICE CONNECTION ISSUE	300	41	171.34	6.63	4.79	9.19	299	41	170.13	6.60	4.76	9.15
INJECTION SITE ERYTHEMA	25149	4680	12825.05	4.87	4.72	5.02	25153	4676	12815.95	4.87	4.72	5.02
INTENTIONAL DOSE OMISSION	72	7	45.88	9.32	4.29	20.26	72	7	45.81	9.31	4.29	20.24
PRODUCT LABEL CONFUSION	44	3	30.31	13.30	4.13	42.82	44	3	30.27	13.28	4.12	42.77
VACCINATION SITE WARMTH	2694	547	1228.41	4.46	4.07	4.89	2692	547	1224.64	4.46	4.07	4.88
INJECTION SITE												
HYPERSENSITIVITY	149	21	83.06	6.43	4.07	10.16	149	21	82.93	6.42	4.07	10.14
VACCINATION SITE PRURITUS	3251	670	1467.92	4.40	4.05	4.78	3250	668	1467.83	4.41	4.05	4.79
INJECTION SITE URTICARIA	1264	251	583.40	4.57	3.99	5.23	1263	251	581.58	4.56	3.98	5.22
INJECTION SITE REACTION	3976	847	1752.94	4.26	3.95	4.58	3977	844	1755.46	4.27	3.96	4.59
VACCINATION SITE RASH	2050	429	912.01	4.33	3.90	4.81	2050	428	912.01	4.34	3.91	4.81
VACCINATION SITE REACTION	1029	206	471.66	4.53	3.90	5.26	1029	206	470.83	4.52	3.90	5.25
INJECTION SITE												
INFLAMMATION	866	176	392.21	4.46	3.79	5.24	866	176	391.51	4.46	3.79	5.24
POOR QUALITY PRODUCT												
ADMINISTERED	790	161	356.88	4.45	3.76	5.27	789	154	367.22	4.64	3.90	5.51
INDURATION	1685	381	703.29	4.01	3.59	4.48	1683	381	700.42	4.00	3.58	4.47
INJECTION SITE SWELLING	19462	4790	7854.72	3.68	3.57	3.80	19462	4782	7852.49	3.69	3.57	3.80
VACCINATION SITE												
LYMPHADENOPATHY	151	26	75.34	5.26	3.47	7.98	151	26	75.22	5.26	3.47	7.97
INJECTION SITE PAPULE	53	6	31.58	8.01	3.44	18.63	53	6	31.53	8.00	3.44	18.61
VACCINATION COMPLICATION	2206	537	863.67	3.72	3.39	4.09	2207	537	862.74	3.72	3.39	4.09
INJECTION SITE CELLULITIS	324	67	143.90	4.38	3.37	5.70	325	67	144.42	4.39	3.38	5.71
EXPIRED PRODUCT												
ADMINISTERED	11238	2933	4202.59	3.47	3.34	3.62	11176	2905	4187.67	3.48	3.35	3.63
INJECTION SITE IRRITATION	257	52	115.76	4.48	3.33	6.04	257	52	115.56	4.48	3.32	6.03
VACCINATION SITE ERYTHEMA	4830	1246	1800.09	3.51	3.30	3.74	4826	1244	1796.37	3.51	3.30	3.74
INJECTION SITE MASS	2285	666	741.28	3.11	2.85	3.30	2283	666	738.24	3.10	2.85	3.38

LOCAL REACTION	230	55	90.12	3.29	2.83	5.09	230	54	91.45	3.86	2.87	5.19
CELLULITIS	982	277	329.19	3.21	2.81	3.67	983	277	329.20	3.21	2.81	3.67
SKIN WARM	6657	2069	2018.86	2.92	2.78	3.06	6661	2067	2019.55	2.92	2.78	3.06
PRODUCT ADMINISTRATION INTERRUPTED	30	3	18.06	9.07	2.77	29.70	30	3	18.03	9.06	2.76	29.67
MATERNAL EXPOSURE DURING PREGNANCY	706	199	236.43	3.22	2.75	3.76	706	197	238.60	3.25	2.77	3.80
VACCINATION SITE URTICARIA	249	64	91.15	3.53	2.68	4.64	249	64	90.96	3.52	2.68	4.64
POST-ACUTE COVID-19 SYNDROME	210	53	78.09	3.59	2.66	4.85	210	51	80.86	3.73	2.75	5.06
SKIN INDURATION	159	38	61.98	3.79	2.66	5.40	159	37	63.36	3.89	2.72	5.56
INJECTION SITE NODULE	886	266	277.20	3.03	2.64	3.47	886	264	277.83	3.04	2.65	3.49
INJECTION SITE INDENTATION	97	21	40.71	4.19	2.61	6.71	97	21	40.63	4.18	2.61	6.70
SKIN REACTION	538	160	168.95	3.05	2.56	3.64	537	159	169.16	3.06	2.56	3.65
INJECTION SITE OEDEMA	170	44	61.44	3.50	2.51	4.88	168	44	59.86	3.46	2.48	4.82
VACCINATION SITE DISCOLOURATION	257	72	85.91	3.24	2.49	4.20	256	72	85.02	3.22	2.48	4.18
VACCINATION SITE MOVEMENT IMPAIRMENT	260	75	84.08	3.14	2.43	4.06	260	75	83.89	3.14	2.43	4.06
INJECTION SITE DISCOLOURATION	467	155	126.95	2.73	2.28	3.28	465	155	125.33	2.72	2.27	3.26
VACCINATION SITE SWELLING	3716	1395	847.71	2.41	2.27	2.57	3710	1394	842.75	2.41	2.27	2.56
VACCINATION SITE DISCHARGE	41	8	17.92	4.65	2.18	9.91	41	8	17.89	4.64	2.18	9.90
RASH ERYTHEMATOUS	7149	2912	1421.35	2.23	2.13	2.32	7147	2904	1423.51	2.23	2.14	2.33
EXPOSURE VIA BREAST MILK	52	12	20.15	3.93	2.10	7.36	52	12	20.11	3.92	2.09	7.35
PRODUCT AVAILABILITY ISSUE	23	3	12.11	6.95	2.09	23.15	23	3	12.09	6.94	2.08	23.12
ERYTHEMA	15381	6692	2735.48	2.08	2.03	2.14	15363	6674	2732.54	2.08	2.03	2.14
ERYTHEMA MULTIFORME	123	39	34.87	2.86	1.99	4.10	122	39	34.12	2.83	1.98	4.06
CHRONIC SPONTANEOUS URTICARIA	99	30	29.57	2.99	1.99	4.50	97	29	29.37	3.03	2.00	4.59
SKIN SWELLING	476	184	101.72	2.35	1.98	2.78	474	183	101.23	2.35	1.98	2.78
INJECTION SITE INFECTION	104	32	30.51	2.95	1.98	4.38	104	32	30.44	2.94	1.98	4.37
INJECTION SITE STREAKING	46	11	17.13	3.79	1.96	7.32	46	11	17.09	3.79	1.96	7.31
EXPOSURE VIA SKIN CONTACT	118	38	32.72	2.82	1.95	4.06	118	38	32.64	2.81	1.95	4.05
INJECTION SITE ABSCESS	80	24	24.01	3.02	1.92	4.77	80	24	23.95	3.02	1.91	4.76
SKIN INFECTION	60	19	16.56	2.86	1.71	4.80	61	19	17.19	2.91	1.74	4.87
URTICARIA CHRONIC	106	40	22.98	2.40	1.67	3.46	102	40	20.56	2.31	1.60	3.33
ANTIBODY TEST NEGATIVE	24	5	9.50	4.35	1.66	11.40	24	5	9.48	4.35	1.66	11.39
VACCINATION SITE INFLAMMATION	154	64	28.21	2.18	1.63	2.92	154	64	28.12	2.18	1.63	2.92
INJECTION SITE PUSTULE	36	10	11.27	3.26	1.62	6.58	36	10	11.25	3.26	1.62	6.57
VACCINATION SITE CELLULITIS	42	13	11.67	2.93	1.57	5.46	42	13	11.64	2.93	1.57	5.45
INJECTION SITE MACULE	23	5	8.00	3.99	1.51	10.53	23	5	7.98	3.98	1.51	10.52
INJECTION SITE EXTRAVASATION	91	38	16.22	2.17	1.49	3.17	91	38	16.16	2.17	1.49	3.17
INJECTION SITE LYMPHADENOPATHY	82	36	13.07	2.06	1.40	3.06	82	36	13.02	2.06	1.39	3.05
INJECTION SITE SCAR	35	12	8.27	2.64	1.37	5.09	35	12	8.25	2.64	1.37	5.09
GENERALISED OEDEMA	23	6	6.65	3.32	1.35	8.20	23	6	6.63	3.32	1.35	8.19
MASS EXCISION	15	3	5.70	4.53	1.31	15.66	15	3	5.69	4.53	1.31	15.64
INJECTION RELATED REACTION	17	4	5.75	3.85	1.30	11.45	17	4	5.73	3.85	1.29	11.44
OROPHARYNGEAL DISORDER	17	4	5.75	3.85	1.30	11.45	17	4	5.73	3.85	1.29	11.44
EYE COLOUR CHANGE	19	5	5.84	3.44	1.29	9.23	19	5	5.83	3.44	1.28	9.22
LIMB IMMOBILISATION	31	11	6.85	2.55	1.28	5.08	31	11	6.83	2.55	1.28	5.08
VACCINATION SITE SCAR	25	8	6.38	2.83	1.28	6.28	25	7	7.44	3.23	1.40	7.48
URINE OUTPUT INCREASED	21	6	5.97	3.17	1.28	7.86	21	6	5.95	3.17	1.28	7.85

INJECTION SITE SCAB	56	25	8.39	2.03	1.27	3.25	56	25	8.36	2.03	1.27	3.25
FEELING OF RELAXATION	9	9	5.84	2.62	1.23	5.59	26	9	5.83	2.62	1.23	5.58
PTIA/TOM LIMB SYNDROME	22	7	5.47	2.85	1.22	6.67	22	7	5.46	2.85	1.22	6.66
MULTIPLE USE OF SINGLE-USE PRODUCT	14	3	4.95	4.23	1.22	14.72	14	3	4.94	4.23	1.21	14.70
GINGIVITIS	20	6	5.30	3.02	1.21	7.52	20	6	5.29	3.02	1.21	7.52
MYOCLEROSIS	36	15	6.02	2.18	1.19	3.97	36	15	6.00	2.17	1.19	3.97
EPILEPSY	34	14	5.79	2.20	1.18	4.10	34	14	5.77	2.20	1.18	4.10
ABSCESS LIMB	17	5	4.49	3.08	1.14	8.35	17	5	4.47	3.08	1.14	8.34
ECZEMA NUMMULAR	15	4	4.34	3.40	1.13	10.24	15	4	4.33	3.40	1.13	10.23
DENTAL DISCOMFORT	34	15	4.98	2.05	1.12	3.77	34	15	4.96	2.05	1.12	3.77
TOOTH LOSS	13	3	4.23	3.93	1.12	13.79	13	3	4.22	3.92	1.12	13.77
SKIN PLAQUE	27	11	4.55	2.23	1.10	4.49	27	11	4.54	2.22	1.10	4.48
ACCIDENTAL UNDERDOSE	197	1	173.88	178.59	25.03	1274.11	193	1	170.06	174.76	24.49	1246.95
ANAESTHESIA	19	1	12.86	17.22	2.31	128.66	19	1	12.85	17.20	2.30	128.52
VACCINATION SITE	19	1	12.86	17.22	2.31	128.66	19	1	12.85	17.20	2.30	128.52
DYSAESTHESIA	16	2	8.18	7.25	1.67	31.54	16	2	8.16	7.24	1.67	31.50
VACCINATION SITE	13	2	5.74	5.89	1.33	26.11	13	2	5.73	5.89	1.33	26.08
HYPERSENSITIVITY	11	2	4.18	4.99	1.11	22.49	11	2	4.17	4.98	1.10	22.47
PRODUCT EXPIRATION DATE	9	1	4.25	8.16	1.03	64.40	9	1	4.24	8.15	1.03	64.32
VACCINATION SITE STREAKING	19	1	12.86	17.22	2.31	128.66	19	1	12.22	4.53	0.53	38.75
SARS-COV-2 ANTIBODY TEST												
PRODUCT CONTAMINATION												
PHYSICAL												

PREFERRED Medical Dictionary for Regulatory Activities (MedDRA) Terms (VAERS-1 Box 7, VAERS 2.0 Box 18)

For Current Week and Past Week Comparison

Following ALL 12/14/2020-04/01/2022 COVID19 Pfizer Ages 18+ Vaccines

Compared to ALL 12/14/2020-04/01/2022 COVID19 Moderna Ages 18+ Vaccines

AGES 18+ YEARS, Initial domestic reports only, VAERS reports as of 04/01/2022

Vaccination, Received, and Completed Date: 12/14 - 04/01 (Current Week) and 12/14 - 03/25 (Past Week)

N>=3 (Current Week), PRR=2.00 (Ratio of Proportions), Chi-Square=4.00

MedDRA PT's sorting based on lower confidence limit and PFIZER adverse event count from 12/14/2020-04/01/2022

AGES 18+ YEARS excludes missing ages

MedDRA Codes ALL Reports (18+)	12/14/2020- 04/01/2022 PFIZER N=301241	12/14/2020- 04/01/2022 MODERNA N=321994	12/14-04/01 Chi-Square	12/14-04/01 PRR	12/14-04/01 LCL	12/14-04/01 UCL	12/14/2020- 03/25/2022 PFIZER N=299926	12/14/2020- 03/25/2022 MODERNA N=320915	12/14-03/25 Chi-Square	12/14-03/25 PRR	12/14-03/25 LCL	12/14-03/25 UCL
PRODUCT PREPARATION ERROR	558	15	550.52	39.76	23.81	66.40	559	15	552.19	39.87	23.88	66.59
VACCINATION FAILURE	953	45	888.21	22.64	16.79	30.52	939	41	885.21	24.51	17.93	33.50
PRODUCT USE ISSUE	431	27	382.66	17.06	11.57	25.17	431	27	383.10	17.08	11.58	25.20
PRODUCT PREPARATION ISSUE	2107	167	1793.53	13.49	11.52	15.79	2105	167	1793.57	13.49	11.52	15.79
DISEASE RECURRENCE	215	11	196.40	20.89	11.40	38.29	214	11	195.56	20.82	11.36	38.15
IMMUNISATION	2512	215	2100.56	12.49	10.87	14.35	2508	215	2098.90	12.48	10.86	14.35
CIRCUMSTANCE OR INFORMATION CAPABLE OF LEADING TO MEDICATION ERROR	123	17	86.01	7.73	4.66	12.84	123	17	86.13	7.74	4.66	12.86
OFF LABEL USE	965	211	535.20	4.89	4.21	5.67	959	210	532.14	4.89	4.21	5.67
IMMUNODEFICIENCY	481	105	266.14	4.90	3.96	6.05	480	103	269.15	4.99	4.03	6.17
DRUG INEFFECTIVE	1014	259	499.80	4.18	3.65	4.80	1003	253	500.32	4.24	3.70	4.87
APPARENT LIFE THREATENING EVENT	64	10	41.62	6.84	3.51	13.32	63	10	40.69	6.74	3.46	13.14
INCORRECT PRODUCT FORMULATION ADMINISTERED	548	162	235.72	3.62	3.03	4.31	548	162	236.15	3.62	3.04	4.31
MIDDLE INSOMNIA	75	17	39.26	4.72	2.79	7.98	74	17	38.40	4.66	2.75	7.89
OVERDOSE	176	56	69.32	3.36	2.49	4.54	174	55	69.15	3.39	2.50	4.58
WHITE BLOOD CELL COUNT INCREASED	111	36	42.40	3.30	2.26	4.80	110	36	41.66	3.27	2.24	4.76
INTERACTANT OF VACCINE PRODUCTS	5768	2615	1425.09	2.36	2.25	2.47	5760	2592	1445.66	2.38	2.27	2.49
NEAR DEATH EXPERIENCE	105	35	38.81	3.21	2.19	4.70	105	35	38.89	3.21	2.19	4.71
CROHN'S DISEASE	123	45	40.66	2.92	2.08	4.11	122	44	41.17	2.97	2.10	4.19
DRUG HYPERSENSITIVITY	180	71	54.02	2.71	2.06	3.57	178	71	52.66	2.68	2.04	3.53
SKIN DISORDER	265	115	68.89	2.46	1.98	3.07	261	112	69.28	2.49	2.00	3.11
EXPOSURE TO SARS-COV-2	1212	610	241.26	2.12	1.93	2.34	1188	601	234.56	2.12	1.92	2.33
POLYMERORRHOEA	461	219	102.44	2.25	1.92	2.64	462	219	103.37	2.26	1.92	2.65
UTERINE HAEMORRHAGE	64	22	22.40	3.11	1.92	5.05	64	21	23.72	3.26	1.99	5.34
MENSTRUAL DISORDER	1597	838	298.55	2.06	1.90	2.24	1591	836	297.41	2.06	1.90	2.24
BONE DISORDER	490	12	15.89	3.56	1.87	6.79	40	12	15.92	3.57	1.87	6.80
ANTIINJECTABLE ANTIBODY POSITIVE	28	7	12.81	4.28	1.87	9.79	28	7	12.84	4.28	1.87	9.80
CLAUSTROPHOBIA	23	5	11.50	4.92	1.87	12.93	23	5	11.52	4.92	1.87	12.95
MAST CELL ACTIVATION SYNDROME	49	16	17.98	3.27	1.86	5.76	47	16	16.41	3.14	1.78	5.54
INTERMENSTRUAL BLEEDING	860	443	162.48	2.08	1.85	2.33	857	441	162.75	2.08	1.85	2.33
EAR DISORDER	106	43	30.13	2.63	1.85	3.76	105	42	30.55	2.67	1.87	3.83
HYPOEMORRHOEA	115	48	31.34	2.56	1.83	3.59	114	48	30.70	2.54	1.81	3.56
ELECTROCARDIOGRAM ABNORMAL	74	28	22.99	2.82	1.83	4.36	72	27	22.67	2.85	1.83	4.44
PHARYNGEAL INFLAMMATION	17	3	9.35	6.06	1.78	20.67	17	3	9.36	6.06	1.78	20.69

HEMIANÆSTHESIA	18	5	7.09	3.85	1.43	10.36	18	5	7.11	3.85	1.43	10.37
ENDOTRACHEAL INTUBATION COMPLICATION	16	4	6.81	4.28	1.43	12.79	16	4	6.82	4.28	1.43	12.80
NEUTROPHIL COUNT DECREASED	16	4	6.81	4.28	1.43	12.79	16	4	6.82	4.28	1.43	12.80
PNEUMONIA PSEUDOMONAL	14	3	6.57	4.99	1.43	17.36	14	3	5.70	4.64	1.32	16.27
SLEEP DISORDER DUE TO A GENERAL MEDICAL CONDITION	14	3	6.57	4.99	1.43	17.36	14	3	6.59	4.99	1.43	17.37
VISUAL ACUTY REDUCED	50	23	11.09	2.32	1.42	3.81	48	23	9.83	2.23	1.36	3.67
ILANGOVER	58	28	11.82	2.21	1.41	3.48	58	28	11.85	2.22	1.41	3.48
BLADDER DISORDER	51	24	10.84	2.27	1.40	3.69	51	24	10.87	2.27	1.40	3.69
EYE OEDEMA	25	9	7.66	2.97	1.39	6.36	25	9	7.68	2.97	1.39	6.37
SUBMAXILLARY GLAND ENLARGEMENT	25	9	7.66	2.97	1.39	6.36	25	9	7.68	2.97	1.39	6.37
HORMONE LEVEL ABNORMAL	65	33	11.99	2.11	1.38	3.20	64	33	11.43	2.08	1.36	3.16
PROTEINURIA	58	29	10.99	2.14	1.37	3.34	58	28	11.85	2.22	1.41	3.48
CARDIAC VALVE DISEASE	30	12	8.07	2.67	1.37	5.22	30	11	9.18	2.92	1.46	5.82
PHARYNGEAL ULCERATION	23	8	7.30	3.07	1.37	6.87	23	8	7.31	3.08	1.38	6.88
MAGNETIC RESONANCE IMAGING HEART TIC	19	6	6.59	3.38	1.35	8.48	19	5	7.96	4.07	1.52	10.89
INTRACRANIAL PRESSURE INCREASED	49	24	9.58	2.18	1.34	3.56	49	24	9.61	2.18	1.34	3.56
AORTIC DISORDER	41	19	8.83	2.31	1.34	3.97	40	19	8.21	2.25	1.30	3.89
NAIL DISCOLOURATION	17	5	6.26	3.63	1.34	9.85	17	5	6.28	3.64	1.34	9.86
NAIL DISCOLOURATION	58	30	10.19	2.07	1.33	3.21	57	30	9.64	2.03	1.31	3.16
NASAL PRURITUS	58	30	10.19	2.07	1.33	3.21	58	30	10.22	2.07	1.33	3.21
MEASLES	15	4	5.96	4.01	1.33	12.08	15	4	5.97	4.01	1.33	12.09
THYROIDITIS	50	25	9.37	2.14	1.32	3.46	50	25	9.40	2.14	1.32	3.46
STILLBIRTH	39	18	8.42	2.32	1.32	4.05	39	18	8.45	2.32	1.33	4.05
DECREASED NASOLABIAL FOLD	24	9	6.92	2.85	1.32	6.13	24	9	6.93	2.85	1.33	6.14
COLOSTOMY	13	3	5.69	4.63	1.32	16.25	13	3	5.70	4.64	1.32	16.27
PHARYNGITIS STRIPTOCOCCAL	57	30	9.61	2.03	1.31	3.16	57	30	9.64	2.03	1.31	3.16
GESTATIONAL DIABETES	22	8	6.54	2.94	1.31	6.60	22	8	6.55	2.94	1.31	6.61
ELECTROCARDIOGRAM ST SEGMENT ABNORMAL	32	14	7.47	2.44	1.30	4.58	30	13	7.09	2.47	1.29	4.73
ACUTE CARDIAC EVENT	27	11	6.97	2.62	1.30	5.29	27	11	6.99	2.63	1.30	5.29
FEBRILE NEUTROPENIA	35	16	7.62	2.34	1.29	4.22	35	15	8.57	2.50	1.36	4.57
BLOOD THYROID STIMULATING HORMONE INCREASED	30	13	7.08	2.47	1.29	4.73	30	13	7.09	2.47	1.29	4.73
DEPERSONALISATION/DEREALI SATION DISORDER	30	13	7.08	2.47	1.29	4.73	30	13	7.09	2.47	1.29	4.73
NIH STROKE SCALE	33	15	7.21	2.35	1.28	4.33	33	15	7.23	2.35	1.28	4.33
ANKYLOSING SPONDYLITIS	25	10	6.58	2.67	1.28	5.56	25	10	6.59	2.67	1.28	5.57
AZOTÆMIA	36	17	7.38	2.26	1.27	4.03	34	17	6.17	2.14	1.20	3.83
PETIT MAL EPILEPSY	28	12	6.68	2.49	1.27	4.90	28	12	6.69	2.50	1.27	4.91
LABILE BLOOD PRESSURE	18	6	5.81	3.21	1.27	8.08	17	5	6.28	3.64	1.34	9.86
HIFARING AID USER	31	14	6.81	2.37	1.26	4.45	26	13	4.55	2.14	1.10	4.16
PLATELET COUNT INCREASED	31	14	6.81	2.37	1.26	4.45	31	14	6.83	2.37	1.26	4.45
ALANINE AMINOTRANSFERASE INCREASED	40	20	7.36	2.14	1.25	3.66	40	20	7.38	2.14	1.25	3.66
COLECTOMY	37	18	7.16	2.20	1.25	3.86	37	17	8.04	2.33	1.31	4.14
ANTIALLERGIC THERAPY	32	15	6.57	2.28	1.23	4.21	32	15	6.59	2.28	1.24	4.21
WALKING DISABILITY	32	15	6.57	2.28	1.23	4.21	32	15	6.59	2.28	1.24	4.21
BLOOD SODIUM DECREASED	24	10	5.88	2.57	1.23	5.36	24	10	5.90	2.57	1.23	5.37
HÆMOTHORAX	14	4	5.13	3.74	1.23	11.37	14	4	5.14	3.74	1.23	11.38

PARENTERAL NUTRITION	14	4	5.13	3.74	1.23	11.37	13	4	4.33	3.48	1.13	10.66
CORONARY ANGIOPLASTY	27	12	6.01	2.41	1.22	4.75	27	11	6.99	2.63	1.30	5.29
COR PULMONALE	19	7	5.42	2.90	1.22	6.90	19	7	5.43	2.90	1.22	6.91
POSTPARTUM HAEMORRHAGE	19	7	5.42	2.90	1.22	6.90	19	7	5.43	2.90	1.22	6.91
OCULAR ICTERUS	36	18	6.55	2.14	1.21	3.76	36	17	7.40	2.27	1.27	4.03
SICK RELATIVE	36	18	6.55	2.14	1.21	3.76	36	18	6.57	2.14	1.22	3.77
HIPATIC MASS	30	14	6.17	2.29	1.21	4.32	28	14	4.96	2.14	1.13	4.06
UTERINE PAIN	37	19	6.36	2.08	1.20	3.62	37	19	6.38	2.08	1.20	3.62
ABDOMINAL MASS	22	9	5.49	2.61	1.20	5.67	22	8	6.55	2.94	1.31	6.61
PROTEIN URINE PRESENT	17	6	5.05	3.03	1.19	7.68	17	6	5.06	3.03	1.30	7.69
DYSAESTHESIA	35	18	5.96	2.08	1.18	3.67	35	18	5.98	2.08	1.18	3.67
SOCIAL AVOIDANT BEHAVIOUR	20	8	5.09	2.67	1.18	6.07	20	8	5.10	2.67	1.18	6.07
SOMNAMBULISM	20	8	5.09	2.67	1.18	6.07	19	8	4.42	2.54	1.11	5.80
CONVERSION DISORDER	32	16	5.75	2.14	1.17	3.90	32	16	5.76	2.14	1.17	3.90
EPICONDYLITIS	29	14	5.54	2.21	1.17	4.19	29	14	5.56	2.22	1.17	4.19
PELVIC VENOUS THROMBOSIS	26	12	5.36	2.32	1.17	4.59	25	12	4.75	2.23	1.12	4.44
ENDOMETRIAL THICKENING	23	10	5.21	2.46	1.17	5.17	23	10	5.22	2.46	1.17	5.17
INCORRECT PRODUCT ADMINISTRATION DURATION	23	10	5.21	2.46	1.17	5.17	23	10	5.22	2.46	1.17	5.17
PHONOPHOBIA	23	10	5.21	2.46	1.17	5.17	23	10	5.22	2.46	1.17	5.17
COMPLICATED APPENDICITIS	15	5	4.68	3.21	1.17	8.82	15	5	4.69	3.21	1.17	8.83
COMPUTERISED TOMOGRAM	15	5	4.68	3.21	1.17	8.82	15	5	4.69	3.21	1.17	8.83
TIHORAX	15	5	4.68	3.21	1.17	8.82	15	5	4.69	3.21	1.17	8.83
FACTOR V LEIDEN MUTATION	15	5	4.68	3.21	1.17	8.82	15	5	4.69	3.21	1.17	8.83
ELECTROCARDIOGRAM QT PROLONGED	33	17	5.56	2.07	1.16	3.72	32	16	5.76	2.14	1.17	3.90
HYPOSMOLAR STATE	27	13	5.14	2.22	1.15	4.30	27	13	5.16	2.22	1.15	4.31
NIH STROKE SCALE SCORE INCREASED	27	13	5.14	2.22	1.15	4.30	27	13	5.16	2.22	1.15	4.31
ISCHERIC HIA URINARY TRACT INFECTION	18	7	4.70	2.75	1.15	6.58	18	7	4.71	2.75	1.15	6.59
VERTEBRAL ARTERY DISSECTION	18	7	4.70	2.75	1.15	6.58	18	7	4.71	2.75	1.15	6.59
PROXIE POSITION	34	18	5.39	2.02	1.14	3.57	33	17	5.58	2.08	1.16	3.73
BLOOD CREATINIE	24	11	4.96	2.33	1.14	4.76	23	11	4.55	2.24	1.09	4.59
PHOSPHOKINASE INCREASED	24	11	4.96	2.33	1.14	4.76	23	11	4.55	2.24	1.09	4.59
CERVICAL RADICULOPATHY	24	11	4.96	2.33	1.14	4.76	23	11	4.55	2.24	1.09	4.59
INTESTINAL PERFORATION	24	11	4.96	2.33	1.14	4.76	24	11	4.97	2.33	1.14	4.77
BRONCHIAL SECRETION	28	14	4.94	2.14	1.13	4.06	27	14	4.38	2.06	1.08	3.93
RETENTION	13	4	4.32	3.47	1.13	10.65	13	4	4.33	3.48	1.13	10.66
PENILE PAIN	13	4	4.32	3.47	1.13	10.65	13	4	4.33	3.48	1.13	10.66
BLOOD POTASSIUM INCREASED	16	6	4.31	2.85	1.12	7.28	16	6	4.32	2.85	1.12	7.29
CIRRHOSIS ALCOHOLIC	16	6	4.31	2.85	1.12	7.28	16	6	4.32	2.85	1.12	7.29
MICROCYTIC ANAEMIA	29	15	4.76	2.07	1.11	3.85	28	14	4.96	2.14	1.13	4.06
MENINGITIS VIRAL	19	8	4.40	2.54	1.11	5.80	19	8	4.42	2.54	1.11	5.80
ORTHOSTATIC HYPERTENSION	19	8	4.40	2.54	1.11	5.80	19	8	4.42	2.54	1.11	5.80
CLONUS	26	13	4.54	2.14	1.10	4.16	26	12	5.38	2.32	1.17	4.59
PATIENT UNCOOPERATIVE	26	13	4.54	2.14	1.10	4.16	26	13	4.55	2.14	1.10	4.16
LANGUAGE DISORDER	23	11	4.33	2.23	1.09	4.58	23	11	4.35	2.24	1.09	4.59
ILLUSION	20	9	4.15	2.38	1.08	5.22	20	9	4.16	2.38	1.08	5.22
CEREBRAL ARTERY STENOSIS	24	12	4.14	2.14	1.07	4.27	24	12	4.15	2.14	1.07	4.28
MENISCUS INJURY	24	12	4.14	2.14	1.07	4.27	24	12	4.15	2.14	1.07	4.28
OVARIAN CYST	94	49	16.65	2.05	1.45	2.90	88	49	13.28	1.92	1.36	2.73
AUTONOMIC NERVOUS SYSTEM	94	49	16.65	2.05	1.45	2.90	88	49	13.28	1.92	1.36	2.73
IMBALANCE	93	49	16.06	2.03	1.44	2.87	89	49	13.84	1.94	1.37	2.75

RED BLOOD CELL TRANSFUSION	21	8	5.80	2.81	1.24	6.33	13	6	2.32	2.32	0.88	6.10
WOUND INFECTION	24	11	4.96	2.33	1.14	4.76	22	11	3.75	2.14	1.04	4.41
RENAL MASS	21	9	4.80	2.49	1.14	5.45	19	9	3.54	2.26	1.02	4.99
ILEOSTOMY	13	4	4.32	3.47	1.13	10.65	10	4	2.14	2.67	0.84	8.53
FOETAL HYPOKINESIA	32	17	4.99	2.01	1.12	3.62	31	17	4.46	1.95	1.08	3.53
SPINAL DISORDER	29	15	4.76	2.07	1.11	3.85	27	15	3.68	1.93	1.02	3.62
MITRAL VALVE CALCIFICATION	23	10	4.55	2.35	1.11	4.97	21	10	3.94	2.25	1.06	4.77
THYROID PAIN	22	10	4.55	2.35	1.11	4.97	21	10	3.94	2.25	1.06	4.77
MUSCLE RUPTURE	19	8	4.40	2.54	1.11	5.80	17	8	3.13	2.27	0.98	5.27
SPINAL FUSION SURGERY	19	8	4.40	2.54	1.11	5.80	17	8	3.13	2.27	0.98	5.27
ALCOHOL WITHDRAWAL SYNDROME	23	11	4.33	2.23	1.09	4.58	22	11	3.75	2.14	1.04	4.41
BODY HEIGHT DECREASED	55	2	51.03	29.39	7.17	120.50	55	2	51.08	29.42	7.18	120.63
SALIVARY GLAND PAIN	18	2	12.29	9.62	2.23	41.46	18	2	12.30	9.63	2.23	41.50
PNEUMOTHORAX SPONTANEOUS	16	2	10.29	8.55	1.97	37.19	16	2	10.30	8.56	1.97	37.23
ELDERLY	13	2	7.36	6.95	1.57	30.79	13	2	7.37	6.95	1.57	30.82
LYMPHOCYTE COUNT DECREASED	13	2	7.36	6.95	1.57	30.79	13	2	7.37	6.95	1.57	30.82
CEREBROSPINAL FLUID LEAKAGE	11	1	7.37	11.76	1.52	91.07	11	1	7.38	11.77	1.52	91.16
CYST RUPTURE	12	2	6.41	6.41	1.44	28.65	10	1	6.38	10.70	1.37	83.58
HYPOAESTHESIA TIBIAL	12	2	6.41	6.41	1.44	28.65	12	2	6.42	6.42	1.44	28.68
INTERVERTEBRAL DISCITIS	12	2	6.41	6.41	1.44	28.65	12	2	6.42	6.42	1.44	28.68
MENORRHAGIA	12	2	6.41	6.41	1.44	28.65	12	2	6.42	6.42	1.44	28.68
OCULAR VASCULAR DISORDER	12	2	6.41	6.41	1.44	28.65	12	2	6.42	6.42	1.44	28.68
ALOPECIA UNIVERSALIS	10	1	6.37	10.69	1.37	83.50	10	1	6.38	10.70	1.37	83.58
ENTEROBACTER INFECTION	10	1	6.37	10.69	1.37	83.50	9	1	5.39	9.63	1.22	76.01
ACUTE STRESS DISORDER	11	2	5.48	5.88	1.30	26.52	11	2	5.49	5.88	1.30	26.55
BLOOD MAGNESIUM DECREASED	11	2	5.48	5.88	1.30	26.52	11	2	5.49	5.88	1.30	26.55
MUTISM	11	2	5.48	5.88	1.30	26.52	11	2	5.49	5.88	1.30	26.55
CHRONIC PIGMENTED PURPURA	9	1	5.38	9.62	1.22	75.93	9	1	5.39	9.63	1.22	76.01
GASTRITIS EROSIVE	9	1	5.38	9.62	1.22	75.93	9	1	5.39	9.63	1.22	76.01
THERAPEUTIC RESPONSE SHORTENED	9	1	5.38	9.62	1.22	75.93	9	1	5.39	9.63	1.22	76.01
ECHOCARDIOGRAM ABNORMAL	10	2	4.57	5.34	1.17	24.39	10	2	4.58	5.35	1.17	24.42
EYELID CONTUSION	10	2	4.57	5.34	1.17	24.39	10	2	4.58	5.35	1.17	24.42
LOW DENSITY LIPOPROTEIN INCREASED	10	2	4.57	5.34	1.17	24.39	10	2	4.58	5.35	1.17	24.42
PERICARDIAL DISEASE	10	2	4.57	5.34	1.17	24.39	10	2	4.58	5.35	1.17	24.42
ANGLE CLOSURE GLAUCOMA	8	1	4.41	8.55	1.07	68.37	8	1	4.42	8.56	1.07	68.44
NEOPLASM PROGRESSION	8	1	4.41	8.55	1.07	68.37	8	1	4.42	8.56	1.07	68.44
POIKILOCYTOSIS	8	1	4.41	8.55	1.07	68.37	8	1	4.42	8.56	1.07	68.44
RED CELL DISTRIBUTION WIDTH INCREASED	8	1	4.41	8.55	1.07	68.37	8	1	4.42	8.56	1.07	68.44
SALIVARY GLAND MASS	8	1	4.41	8.55	1.07	68.37	8	1	4.42	8.56	1.07	68.44
SCIATIC NERVE INJURY	8	1	4.41	8.55	1.07	68.37	8	1	4.42	8.56	1.07	68.44
VIRAL PHARYNGITIS	8	1	4.41	8.55	1.07	68.37	8	1	4.42	8.56	1.07	68.44
PRODUCT LOT NUMBER ISSUE	25	1	21.93	26.72	3.62	197.21	7	1	3.48	7.49	0.92	60.88
OBSTRUCTIVE SLEEP APNOEA SYNDROME	8	1	4.41	8.55	1.07	68.37	5	1	1.71	5.35	0.63	45.79
COSTOCHONDRITIS	141	76	23.41	1.98	1.50	2.62	141	75	24.24	2.01	1.52	2.66
MENTAL FATIGUE	48	26	7.45	1.97	1.22	3.18	49	26	8.04	2.02	1.25	3.24
SUBCUTANEOUS EMPHYSEMA	21	10	3.93	2.24	1.06	4.77	20	9	4.16	2.38	1.08	5.22
NECROSIS	18	8	3.75	2.41	1.05	5.53	18	7	4.71	2.75	1.15	6.59

POSTURING	23	12	3.57	2.05	1.02	4.12	23	11	4.35	2.24	1.09	4.59
MULTIMORBIDITY	19	9	3.55	2.26	1.02	4.99	19	8	4.42	2.54	1.11	5.80
FOCAL PERITONITIS	9	2	3.69	4.81	1.04	22.26	9	1	5.39	9.63	1.22	76.01
LUNG ADENOCARCINOMA	10	4	2.14	2.67	0.84	8.52	10	2	4.58	5.35	1.17	24.42
RIB DEFORMITY	5	1	1.71	5.34	0.62	45.75	5	0	-	-	-	-

PREFERRED Medical Dictionary for Regulatory Activities (MedDRA) Terms (VAERS - Box 7, VAERS 2.0 Box 18)

For Current Week and Past Week Comparison

Following ALL 12/14/2020-04/01/2022 COVID19 Pfizer Ages 18+ Vaccines

Compared to ALL 12/14/2020-04/01/2022 COVID19 Moderna Ages 18+ Vaccines

Vaccination, Received, and Completed Date: 12/14 - 04/01 (Current Week) and 12/14 - 03/25 (Past Week)

N>=3 (Current Week), PRR=2.00 (Ratio of Proportions), Chi-Square=4.00

MedDRA PTs sorting based on lower confidence limit and PFIZER adverse event count from 12/14/2020-04/01/2022

SERIOUS AGES 18+ YEARS excludes missing ages

MedDRA Codes ALL Reports (SERIOUS 18+)	12/14/2020- 04/01/2022 PFIZER N=36199	12/14/2020- 04/01/2022 MODERNA N=29626	12/14-04/01 Chi-Square	12/14-04/01 PRR	12/14-04/01 LCL	12/14-04/01 UCL	12/14/2020- 03/25/2022 PFIZER N=35833	12/14/2020- 03/25/2022 MODERNA N=29263	12/14-03/25 Chi-Square	12/14-03/25 PRR	12/14-03/25 LCL	12/14-03/25 UCL
IMMUNISATION	130	8	84.32	13.30	6.51	27.15	130	8	84.11	13.27	6.50	27.09
VACCINATION FAILURE	64	5	38.38	10.48	4.22	26.02	63	3	41.97	17.15	5.39	54.60
APPARENT LIFE-THREATENING EVENT	61	7	31.75	7.13	3.26	15.59	60	7	30.89	7.00	3.20	15.31
DRUG INEFFECTIVE	106	25	34.60	3.47	2.24	5.36	106	25	34.46	3.46	2.24	5.35
WHITE BLOOD CELL COUNT INCREASED	45	8	17.99	4.60	2.17	9.76	44	8	17.21	4.49	2.11	9.54
DISEASE RECURRENCE	33	5	14.32	5.40	2.11	13.83	33	5	14.27	5.39	2.10	13.80
VIBRATORY SENSE INCREASED	23	3	10.46	6.27	1.88	20.90	23	3	10.42	6.26	1.88	20.85
OFF LABEL USE	74	21	19.24	2.88	1.78	4.68	74	21	19.16	2.88	1.77	4.67
EATING DISORDER	43	12	11.04	2.93	1.55	5.56	43	12	10.99	2.93	1.54	5.55
OSTEOPENIA	27	7	7.24	3.16	1.37	7.25	27	7	7.21	3.15	1.37	7.23
PERTONITIS	31	9	7.31	2.82	1.34	5.92	30	9	6.69	2.72	1.29	5.73
BLOOD CHOLESTEROL INCREASED	24	6	6.61	3.27	1.34	8.01	24	6	6.58	3.27	1.34	7.99
MYO CARDIAC DEATH EXPERIENCE VIRTEBRAL ARTERY DISSECTION	46	16	8.48	2.35	1.33	4.16	46	16	8.44	2.35	1.33	4.15
	16	3	5.43	4.26	1.27	14.98	16	3	5.41	4.26	1.27	14.95
PHOTOSENSITIVITY REACTION	34	7	5.43	2.81	1.21	6.51	33	7	4.83	2.68	1.15	6.35
MUSCLE FATIGUE	32	11	5.80	2.38	1.20	4.72	32	11	5.77	2.38	1.20	4.71
VIRAL SEPSIS	17	4	4.72	3.48	1.17	10.34	16	4	4.08	3.27	1.09	9.77
RENAL TRANSPLANT	21	6	4.78	2.86	1.16	7.10	20	5	5.32	3.27	1.33	8.70
BASAL GANGLIA INFARCTION	27	9	5.04	2.46	1.15	5.22	27	9	5.02	2.45	1.15	5.21
BREAST CANCER FEMALE	30	11	4.77	2.23	1.12	4.45	28	10	4.61	2.29	1.11	4.71
QUALITY OF LIFE DECREASED	30	11	4.77	2.23	1.12	4.45	30	11	4.74	2.23	1.12	4.44
COLECTOMY	35	14	4.71	2.05	1.10	3.80	35	13	5.50	2.20	1.16	4.15
SALIVARY HYPERSECRETION	22	7	4.30	2.57	1.10	6.02	22	7	4.27	2.57	1.10	6.01
DECREASED NASOLABIAL FOLD	20	6	4.21	2.73	1.10	6.79	20	6	4.19	2.72	1.09	6.78
FACIAL SPASM	14	3	4.10	3.82	1.10	13.29	14	3	4.08	3.81	1.10	13.26
ENDOTRACHEAL INTUBATION COMPLICATION	16	4	4.09	3.27	1.09	9.79	16	4	4.08	3.27	1.09	9.77
VOCAL CORD PARALYSIS	16	4	4.09	3.27	1.09	9.79	16	4	4.08	3.27	1.09	9.77
MASTICATION DISORDER	27	10	4.14	2.21	1.07	4.56	27	10	4.11	2.20	1.07	4.55
POSTURAL ORTHOSTATIC TACHYCARDIA SYNDROME	64	26	8.82	2.01	1.28	3.18	60	26	6.96	1.88	1.19	2.99
MAST CELL ACTIVATION SYNDROME	19	5	4.73	3.11	1.16	8.33	17	5	3.54	1.02	1.02	7.53
HYPATIC MASS	26	9	4.52	2.36	1.11	5.04	24	9	3.49	2.18	1.01	4.68
NORMAL LABOUR	26	9	4.52	2.36	1.11	5.04	25	9	3.98	2.27	1.06	4.86
BLOOD DISORDER	24	8	4.10	3.82	1.10	5.46	23	8	3.85	2.35	1.05	5.25
PNEUMONIA PNEUMONIAL	14	3	4.10	3.82	1.10	13.29	13	3	3.44	3.54	1.01	12.42
VEN DISORDER	14	3	4.10	3.82	1.10	13.29	13	3	3.44	3.54	1.01	12.42

SPINAL FUSION SURGERY	16	4	4.09	3.27	1.09	9.79	14	4	2.86	0.94	8.68
PRODUCT USE ISSUE	28	2	16.31	11.46	2.73	48.09	28	2	11.43	2.72	47.99
LIVE BIRTH	21	2	10.83	8.59	2.02	36.65	21	2	8.57	2.01	36.57
MENISCUS INJURY	14	1	7.43	11.46	1.51	87.13	14	1	11.43	1.50	86.94
PNEUMOTHORAX											
SPONTANEOUS	15	2	6.31	6.14	1.40	26.84	15	2	6.12	1.40	26.78
ELDERLY	13	1	6.65	10.64	1.39	81.33	13	1	6.63	1.39	81.15
CLUSTER HEADACHE	12	2	4.17	4.91	1.10	21.94	12	2	4.90	1.10	21.89
BODY TEMPERATURE											
FLUCTUATION	12	2	4.17	4.91	1.10	21.94	11	2	4.49	1.00	20.26
ENTEROBACTER INFECTION	10	1	4.37	8.18	1.05	63.93	9	1	3.63	0.93	58.01
MOANING	63	26	8.35	1.98	1.26	3.13	63	25	9.09	1.30	3.27
CONVULSIVE PLASMA											
TRANSFUSION	42	18	4.87	1.91	1.10	3.32	42	17	5.58	1.15	3.54
SINUS PAIN	26	10	3.65	2.15	1.03	4.41	27	9	5.02	1.15	5.21
CROHN'S DISEASE	32	14	3.38	1.87	1.00	3.50	32	13	4.07	1.06	3.83
ARTERIAL DISORDER	10	2	2.83	4.09	0.90	18.67	10	1	4.36	1.05	63.79
MASS EXCISION	5	1	0.97	4.09	0.48	35.02	5	0	-	-	-

PREFERRED Medical Dictionary for Regulatory Activities (MedDRA) Terms (VAERS-1 Box 7, VAERS 2.0 Box 18)

For Current Week and Past Week Comparison

Following **ALL 12/14/2020-04/01/2022 COVID19 Pfizer Ages 18+ Vaccines**

Compared to **ALL 12/14/2020-04/01/2022 COVID19 Moderna Ages 18+ Vaccines**

NON-SERIOUS AGES 18+ YEARS, Initial domestic reports only, VAERS reports as of 04/01/2022

Vaccination, Received, and Completed Date: 12/14 - 04/01 (Current Week) and 12/14 - 03/25 (Past Week)

N>=3 (Current Week), PRR>=2.00 (Ratio of Proportions), Chi-Square>=4.00

MedDRA PTs sorting based on lower confidence limit and PFIZER adverse event count from 12/14/2020-04/01/2022

NON-SERIOUS AGES 18+ YEARS excludes missing ages

MedDRA Codes ALL Reports (NON-SERIOUS 18+)	12/14/2020- 04/01/2022 PFIZER N=265042	12/14/2020- 04/01/2022 MODERNA N=292368	12/14-04/01 Chi-Square	12/14-04/01 PRR	12/14-04/01 LCL	12/14-04/01 UCL	12/14/2020- 03/25/2022 PFIZER N=264093	12/14/2020- 03/25/2022 MODERNA N=291652	12/14-03/25 Chi-Square	12/14-03/25 PRR	12/14-03/25 LCL	12/14-03/25 UCL
PRODUCT PREPARATION ERROR	554	15	564.74	40.74	24.40	68.04	555	15	566.52	40.86	24.47	68.24
VACCINATION FAILURE	889	40	862.95	24.52	17.86	33.65	876	38	855.25	25.46	18.40	35.23
DISEASE RECURRENT	182	6	181.00	33.46	14.84	75.46	181	6	180.12	33.31	14.77	75.14
PRODUCT PREPARATION ISSUE	2104	167	1857.71	13.90	11.87	16.27	2102	167	1857.99	13.90	11.87	16.27
PRODUCT USE ISSUE	403	25	371.25	17.78	11.87	26.63	403	25	371.72	17.80	11.89	26.66
IMMUNISATION	2382	207	2059.39	12.69	11.01	14.63	2378	207	2057.81	12.69	11.01	14.62
IMMUNODEFICIENCY	410	60	295.46	7.54	5.75	9.88	410	58	300.20	7.81	5.93	10.28
CIRCUMSTANCE OR INFORMATION CAPABLE OF LEADING TO MEDICATION ERROR	117	17	83.39	7.59	4.56	12.63	117	17	83.52	7.60	4.57	12.64
OFF LABEL USE	891	190	526.80	5.17	4.42	6.05	885	189	523.61	5.17	4.42	6.05
DRUG INEFFECTIVE	908	234	467.42	4.28	3.71	4.94	897	228	467.76	4.34	3.76	5.02
INCORRECT PRODUCT FORMULATION ADMINISTERED	546	162	247.35	3.72	3.12	4.43	546	162	247.84	3.72	3.12	4.44
MIDDLE INSOMNIA	72	15	41.85	5.29	3.04	9.23	71	15	40.95	5.23	3.00	9.12
OVERDOSE	151	46	65.76	3.62	2.60	5.04	149	46	64.13	3.58	2.57	4.98
INTERCHANGE OF VACCINE PRODUCTS	5707	2558	1554.26	2.46	2.35	2.58	5700	2535	1576.89	2.48	2.37	2.60
DRUG HYPERSENSITIVITY	148	55	51.34	2.97	2.18	4.04	147	55	50.66	2.95	2.17	4.02
CROHN'S DISEASE	91	31	34.70	3.24	2.15	4.87	90	31	33.94	3.21	2.13	4.82
UPPER RESPIRATORY TRACT CONGESTION	93	34	32.57	3.02	2.04	4.47	92	34	31.83	2.99	2.02	4.43
NEAR DEATH EXPERIENCE	59	19	23.57	3.43	2.04	5.74	59	19	23.62	3.43	2.04	5.75
EXPOSURE TO SARS-COV-2	775	373	182.96	2.29	2.03	2.59	756	368	175.18	2.27	2.00	2.57
SKIN DISORDER	230	99	65.10	2.56	2.02	3.24	227	97	65.15	2.58	2.04	3.28
UTERINE HAEMORRHAGE	56	18	22.36	3.43	2.02	5.84	56	17	23.79	3.64	2.11	6.26
EAR DISORDER	92	34	31.76	2.98	2.01	4.42	91	33	32.25	3.05	2.04	4.54
POLYMERORRHOEA	445	208	110.40	2.36	2.00	2.78	446	208	111.40	2.37	2.01	2.79
MENSTRUAL DISORDER	1553	806	316.82	2.13	1.95	2.31	1550	805	316.75	2.13	1.95	2.32
INTERMENSTRUAL BLEEDING	847	431	179.36	2.17	1.93	2.43	844	429	179.68	2.17	1.93	2.44
ASYMPTOMATIC COVID-19	321	151	78.47	2.35	1.93	2.85	318	151	76.62	2.33	1.92	2.82
HYPOMENORRHOEA	113	46	34.34	2.71	1.92	3.82	112	46	33.67	2.69	1.91	3.79
STRIDOR	75	28	25.37	2.95	1.91	4.56	75	28	25.43	2.96	1.92	4.57
HEAVY MENSTRUAL BLEEDING	2594	1428	465.81	2.00	1.88	2.14	2582	1420	466.30	2.01	1.88	2.14
MENSTRUATION IRREGULAR	1996	1090	364.44	2.02	1.88	2.17	1986	1087	361.92	2.02	1.87	2.17
ELECTROCARDIOGRAM ABNORMAL	39	12	15.97	3.59	1.88	6.85	38	11	16.54	3.82	1.95	7.46
NERVE COMPRESSION	122	52	34.64	2.59	1.87	3.58	121	51	35.04	2.62	1.89	3.63
DYSMENORRHOEA	1125	610	207.99	2.03	1.84	2.24	1120	610	205.64	2.03	1.84	2.24
FIBRIN D DIMER INCREASED	50	18	17.38	3.06	1.79	5.25	50	17	18.67	3.25	1.87	5.63

REFUSAL OF TREATMENT BY PATIENT	76	31	22.72	2.70	1.78	4.11	76	31	22.78	2.71	1.78	4.11
ANTINUCLEAR ANTIBODY POSITIVE	19	4	9.97	5.24	1.78	15.40	19	4	9.99	5.25	1.78	15.42
SUSPECTED COVID-19	250	126	53.36	2.19	1.77	2.71	244	125	50.50	2.16	1.74	2.67
EYE OEDEMA	23	6	10.49	4.23	1.72	10.38	23	6	10.51	4.23	1.72	10.40
RED BLOOD CELL COUNT DECREASED	23	6	10.49	4.23	1.72	10.38	23	6	10.51	4.23	1.72	10.40
ANTIALLERGIC THERAPY	16	3	8.82	5.88	1.71	20.19	16	3	8.84	5.89	1.72	20.21
BLOOD THYROID STIMULATING HORMONE INCREASED	27	8	11.13	3.72	1.69	8.19	27	8	11.16	3.73	1.69	8.20
RED BLOOD CELL SEDIMENTATION RATE INCREASED	27	8	11.13	3.72	1.69	8.19	27	8	11.16	3.73	1.69	8.20
WHITE BLOOD CELL COUNT INCREASED	66	28	18.46	2.60	1.67	4.05	66	28	18.51	2.60	1.67	4.05
SUPPRESSED LACTATION	89	41	21.97	2.39	1.65	3.47	89	41	22.03	2.40	1.66	3.47
BODY TEMPERATURE ABNORMAL	105	52	22.76	2.23	1.60	3.11	105	52	22.83	2.23	1.60	3.11
GASTRIC DISORDER	86	41	19.92	2.31	1.60	3.36	85	41	19.30	2.29	1.58	3.32
MEASLES	15	3	7.86	5.52	1.60	19.05	15	3	7.88	5.52	1.60	19.07
PHARYNGEAL MASS	15	3	7.86	5.52	1.60	19.05	15	3	7.88	5.52	1.60	19.07
JAW DISORDER	68	31	16.90	2.42	1.58	3.70	68	31	16.95	2.42	1.58	3.70
LACTATION DISORDER	33	12	10.99	3.03	1.57	5.87	33	12	11.01	3.04	1.57	5.88
WRONG PATIENT	33	12	10.99	3.03	1.57	5.87	35	12	12.63	3.22	1.67	6.20
MOOD ALTERED	104	52	21.26	2.16	1.56	3.01	104	52	22.18	2.21	1.58	3.08
WHITE BLOOD CELL COUNT DECREASED	49	21	13.26	2.57	1.54	4.29	49	20	14.35	2.71	1.61	4.55
FACIAL SPASM	59	27	14.46	2.41	1.53	3.80	59	27	14.50	2.41	1.53	3.81
C-REACTIVE PROTEIN INCREASED	36	14	11.03	2.84	1.53	5.26	36	14	11.05	2.84	1.53	5.26
VAGINAL DISCHARGE	82	41	17.27	2.21	1.52	3.21	82	41	17.32	2.21	1.52	3.21
BASEDOW'S DISEASE	57	26	14.02	2.42	1.52	3.85	55	26	12.69	2.34	1.47	3.72
BONE DISORDER	32	12	10.20	2.94	1.52	5.71	32	12	10.22	2.94	1.52	5.72
MAST CELL ACTIVATION SYNDROME	30	11	9.79	3.01	1.51	6.00	30	11	9.81	3.01	1.51	6.01
UTERINE SPASM	79	40	16.19	2.18	1.49	3.19	78	40	15.60	2.15	1.47	3.15
WALKING DISABILITY	22	7	8.22	3.47	1.48	8.12	22	7	8.24	3.47	1.48	8.12
WEIGHT FLUCTUATION	14	3	6.92	5.15	1.48	17.91	13	3	6.01	4.79	1.36	16.79
SPUTUM DISCOLOURED	68	34	14.19	2.21	1.46	3.33	67	34	13.60	2.18	1.44	3.29
VACCINATION SITE HYPOAESTHESIA	41	18	10.53	2.51	1.44	4.37	41	17	11.57	2.66	1.51	4.69
EPICONDYLITIS	27	10	8.60	2.98	1.44	6.15	27	10	8.62	2.98	1.44	6.16
HANGOVER	57	28	12.20	2.25	1.43	3.53	57	28	12.24	2.25	1.43	3.53
MASTITIS	63	32	12.68	2.17	1.42	3.32	63	32	12.72	2.17	1.42	3.33
ROAD TRAFFIC ACCIDENT	55	27	11.76	2.25	1.42	3.56	55	27	11.80	2.25	1.42	3.57
HAEMOGLOBIN DECREASED	37	16	9.66	2.55	1.42	4.59	37	16	9.69	2.55	1.42	4.59
ANKYLOSING SPONDYLITIS	23	8	7.79	3.17	1.42	7.09	23	8	7.81	3.18	1.42	7.10
OVARIAN CYST	69	36	13.18	2.11	1.41	3.16	66	36	11.40	2.02	1.35	3.04
APRAXIA	19	6	7.01	3.49	1.40	8.75	19	6	7.03	3.50	1.40	8.76
PSORIATIC ARTHROPATHY	51	25	10.89	2.25	1.39	3.63	50	24	11.14	2.30	1.41	3.74
PLATELET COUNT INCREASED	26	10	7.83	2.87	1.38	5.95	26	10	7.85	2.87	1.38	5.95
HORMONE LEVEL ABNORMAL	55	28	10.92	2.17	1.37	3.42	55	28	10.96	2.17	1.38	3.42
PHARYNGITIS STREPTOCOCCAL	50	25	10.24	2.21	1.37	3.57	50	25	10.27	2.21	1.37	3.57
PETIT MAL EPILEPSY	24	9	7.41	2.94	1.37	6.33	24	9	7.43	2.94	1.37	6.34
FRUSTRATION TOLERANCE DECREASED	65	35	11.52	2.05	1.36	3.09	63	34	11.13	2.05	1.35	3.11
SLEEP DISORDER DUE TO A GENERAL MEDICAL CONDITION	13	3	6.00	4.78	1.36	16.77	13	3	6.01	4.79	1.36	16.79

NASAL PRURITUS	57	30	10.56	2.10	1.35	3.26	57	30	10.59	2.10	1.35	3.26
BLOOD CHOLESTEROL INCREASED	54	28	10.30	2.13	1.35	3.36	53	27	10.52	2.17	1.36	3.45
NAIL DISCOLOURATION	52	27	9.86	2.12	1.33	3.38	51	27	9.28	2.09	1.31	3.33
INCREASED APPETITE	53	28	9.68	2.09	1.32	3.30	53	28	9.72	2.09	1.32	3.30
HEPATIC PAIN	54	29	9.52	2.05	1.31	3.23	54	29	9.55	2.06	1.31	3.23
SOMNAMBULISM	18	6	6.19	3.31	1.31	8.34	17	6	5.41	3.13	1.23	7.94
HYPORESPONSIVE TO STIMULI	23	9	6.65	2.82	1.30	6.09	23	9	6.67	2.82	1.31	6.10
SUBMAXILLARY GLAND ENLARGEMENT	23	9	6.65	2.82	1.30	6.09	23	9	6.67	2.82	1.31	6.10
ATELECTASIS	49	26	8.81	2.08	1.29	3.34	49	25	9.64	2.16	1.34	3.50
SINUS BRADYCARDIA	49	26	8.81	2.08	1.29	3.34	48	26	8.25	2.04	1.27	3.29
RETINAL VEIN OCCLUSION	34	16	7.59	2.34	1.29	4.25	34	16	7.61	2.35	1.30	4.25
CLAUSTROPHOBIA	16	5	5.81	3.53	1.29	9.64	16	5	5.82	3.53	1.29	9.65
PHARYNGEAL DISORDER	16	5	5.81	3.53	1.29	9.64	15	5	5.00	3.31	1.20	9.12
THYROIDITIS	44	23	8.11	2.11	1.27	3.49	44	23	8.14	2.11	1.28	3.50
ABNORMAL UTERINE BLEEDING	38	19	7.61	2.21	1.27	3.83	38	19	7.63	2.21	1.27	3.83
CEREBRAL INFARCTION	12	3	5.10	4.41	1.25	15.64	12	3	5.11	4.42	1.25	15.65
SICK RELATIVE	12	3	5.10	4.41	1.25	15.64	12	3	5.11	4.42	1.25	15.65
VIBRATORY SENSE INCREASED	40	21	7.24	2.10	1.24	3.56	40	21	7.27	2.10	1.24	3.57
DEMYELINATION	17	6	5.40	3.13	1.23	7.93	17	6	5.41	3.13	1.23	7.94
MENTAL FATIGUE	42	23	6.92	2.01	1.21	3.35	43	23	7.54	2.06	1.24	3.43
INCORRECT PRODUCT ADMINISTRATION DURATION	23	10	5.63	2.54	1.21	5.33	23	10	5.65	2.54	1.21	5.34
INTRACRANIAL PRESSURE INCREASED	20	8	5.48	2.76	1.21	6.26	21	8	6.24	2.90	1.28	6.54
PHARYNGEAL ULCERATION	20	8	5.48	2.76	1.21	6.26	20	8	5.50	2.76	1.22	6.27
GINGIVAL DISORDER	15	5	4.99	3.31	1.20	9.11	15	5	5.00	3.31	1.20	9.12
ALANINE AMINOTRANSFERASE INCREASED	33	17	6.11	2.14	1.19	3.84	33	17	6.13	2.14	1.19	3.85
TIC	33	17	6.11	2.14	1.19	3.84	33	17	6.13	2.14	1.19	3.85
TOOTH DISORDER	33	17	6.11	2.14	1.19	3.84	32	17	5.52	2.08	1.15	3.74
SINUS ARRHYTHMIA	34	18	5.94	2.08	1.18	3.69	34	18	5.96	2.09	1.18	3.69
UTERINE PAIN	34	18	5.94	2.08	1.18	3.69	34	18	5.96	2.09	1.18	3.69
LABORATORY TEST ABNORMAL	18	7	5.05	2.84	1.18	6.79	17	7	4.34	2.68	1.11	6.47
BLOOD POTASSIUM INCREASED	13	4	4.60	3.59	1.17	10.99	13	4	4.61	3.59	1.17	11.01
NEUTROPHIL COUNT DECREASED	13	4	4.60	3.59	1.17	10.99	13	4	4.61	3.59	1.17	11.01
POLYURIA	35	19	5.78	2.03	1.16	3.55	35	19	5.80	2.03	1.16	3.56
VISUAL ACUITY REDUCED	28	14	5.41	2.21	1.16	4.19	26	14	4.23	2.05	1.07	3.93
NEOPLASM	32	17	5.50	2.08	1.15	3.74	31	17	4.94	2.01	1.11	3.64
BREAST INDURATION	19	8	4.76	2.62	1.15	5.98	19	8	4.77	2.62	1.15	5.99
POST-TRAUMATIC STRESS DISORDER	19	8	4.76	2.62	1.15	5.98	19	8	4.77	2.62	1.15	5.99
ILLUSION	16	6	4.63	2.94	1.15	7.52	16	6	4.64	2.94	1.15	7.53
TOOTH EXTRACTION	16	6	4.63	2.94	1.15	7.52	16	6	4.64	2.94	1.15	7.53
MUSCLE INJURY	26	13	4.97	2.21	1.13	4.29	25	13	4.38	2.12	1.09	4.15
GLUTEN SENSITIVITY	11	3	4.23	4.04	1.13	14.50	11	3	4.24	4.05	1.13	14.51
LANGUAGE DISORDER	11	3	4.23	4.04	1.13	14.50	11	3	4.24	4.05	1.13	14.51
PAROTID GLAND ENLARGEMENT	23	11	4.73	2.31	1.12	4.73	23	11	4.75	2.31	1.13	4.74
BLADDER DISORDER	31	17	4.92	2.01	1.11	3.63	31	17	4.94	2.01	1.11	3.64
POLYARTHRITIS	31	17	4.92	2.01	1.11	3.63	31	17	4.94	2.01	1.11	3.64
ANAL HAEMORRHAGE	14	5	4.21	3.09	1.11	8.57	15	5	5.00	3.31	1.20	9.12
IMMUNISATION ANXIETY RELATED REACTION	14	5	4.21	3.09	1.11	8.57	14	5	4.22	3.09	1.11	8.58

IRIDOCYCLITIS	21	10	4.29	2.32	1.09	4.92	21	10	4.30	2.32	1.09	4.92
OVERSENSING	21	10	4.29	2.32	1.09	4.92	21	10	4.30	2.32	1.09	4.92
TONGUE MOVEMENT												
DISTURBANCE	21	10	4.29	2.32	1.09	4.92	21	10	4.30	2.32	1.09	4.92
LABILE BLOOD PRESSURE	11	3	4.23	4.04	1.13	14.50	11	2	5.76	6.07	1.35	27.40
LIVER DISORDER	30	16	5.07	2.07	1.13	3.79	28	16	3.96	1.93	1.05	3.57
SJOGREN'S SYNDROME	30	16	5.07	2.07	1.13	3.79	28	16	3.96	1.93	1.05	3.57
THYROID PAIN	21	10	4.29	2.32	1.09	4.92	20	10	3.68	2.21	1.03	4.72
BODY HEIGHT DECREASED	50	1	50.13	55.16	7.62	399.26	50	1	50.19	55.22	7.63	399.71
SALIVARY GLAND PAIN	17	2	11.76	9.38	2.17	40.58	17	2	11.78	9.39	2.17	40.63
PHARYNGEAL INFLAMMATION	15	2	9.71	8.27	1.89	36.18	15	2	9.73	8.28	1.89	36.22
BLOOD BILIRUBIN INCREASED	14	2	8.70	7.72	1.75	33.97	14	2	8.71	7.73	1.76	34.01
LYMPHOCYTE COUNT												
DECREASED	12	1	8.73	13.24	1.72	101.80	12	1	8.74	13.25	1.72	101.92
VENOUS THROMBOSIS	12	2	6.72	6.62	1.48	29.57	12	2	6.73	6.63	1.48	29.61
BRAIN NEOPLASM	10	1	6.65	11.03	1.41	86.17	9	1	5.63	9.94	1.26	78.45
HYPOAESTHESIA TEETH	10	1	6.65	11.03	1.41	86.17	10	1	6.66	11.04	1.41	86.27
GESTATIONAL DIABETES	11	2	5.75	6.07	1.34	27.37	11	2	5.76	6.07	1.35	27.40
POTENTIATING DRUG												
INTERACTION	9	1	5.62	9.93	1.26	78.36	9	1	5.63	9.94	1.26	78.45
WOUND DRAINAGE	9	1	5.62	9.93	1.26	78.36	9	1	5.63	9.94	1.26	78.45
CLONUS	10	2	4.81	5.52	1.21	25.17	10	2	4.82	5.52	1.21	25.20
CYST RUPTURE	10	2	4.81	5.52	1.21	25.17	9	1	5.63	9.94	1.26	78.45
HYPOMAGNETSAEMIA	10	2	4.81	5.52	1.21	25.17	10	2	4.82	5.52	1.21	25.20
ALOPECIA UNIVERSALIS	8	1	4.62	8.82	1.10	70.56	8	1	4.63	8.83	1.11	70.64
AORTIC DILATATION	8	1	4.62	8.82	1.10	70.56	8	1	4.63	8.83	1.11	70.64
CEREBROSPINAL FLUID												
LEAKAGE	8	1	4.62	8.82	1.10	70.56	8	1	4.63	8.83	1.11	70.64
CHRONIC PIGMENTED PURPURA	8	1	4.62	8.82	1.10	70.56	8	1	4.63	8.83	1.11	70.64
INFLAMMATORY MARKER												
INCREASED	8	1	4.62	8.82	1.10	70.56	8	1	4.63	8.83	1.11	70.64
THERAPEUTIC RESPONSE												
SHORTENED	8	1	4.62	8.82	1.10	70.56	8	1	4.63	8.83	1.11	70.64
BRAIN INJURY	10	2	4.81	5.52	1.21	25.17	9	2	3.90	4.97	1.07	23.00
ACUTE RESPIRATORY FAILURE	15	6	3.89	2.76	1.07	7.11	14	5	4.22	3.09	1.11	8.58
IMMUNOGLOBULIN THERAPY	20	10	3.66	2.21	1.03	4.71	20	9	4.52	2.45	1.12	5.39
PELVIC FLUID COLLECTION	5	1	1.81	5.52	0.64	47.21	5	0	-	-	-	-

VAERS Pre-specified Conditions for COVID19 Reports, Automated Data (non-reviewed)
Initial domestic reports only, VAERS reports as of 04/01/2022 at 3PM

1

Condition	Age group							Total
	0-17	18-49	50-64	65-74	75-84	85+	UNK	
Acute Myocardial Infarction	20(00.6%)	666(20.3%)	798(24.3%)	766(23.3%)	516(15.7%)	301(09.2%)	215(06.6%)	3282
Anaphylaxis	85(03.2%)	1437(53.6%)	657(24.5%)	214(08.0%)	64(02.4%)	11(00.4%)	212(07.9%)	2680
Appendicitis	81(09.3%)	469(54.1%)	186(21.5%)	78(09.0%)	18(02.1%)	3(00.3%)	32(03.7%)	867
Bells Palsy	136(02.2%)	2443(39.7%)	1731(28.1%)	940(15.3%)	416(06.8%)	195(03.2%)	299(04.9%)	6160
COVID19								.
Coagulopathy	151(01.3%)	3638(30.5%)	3127(26.2%)	2283(19.1%)	1251(10.5%)	492(04.1%)	995(08.3%)	11937
Death	67(00.5%)	1010(07.4%)	2134(15.6%)	3100(22.6%)	3352(24.5%)	2860(20.9%)	1169(08.5%)	13692
Guillian-Barre Syndrome	28(02.5%)	372(33.4%)	333(29.9%)	173(15.5%)	87(07.8%)	17(01.5%)	103(09.3%)	1113
Kawasaki Disease	12(80.0%)	2(13.3%)		1(06.7%)				15
Multisystem Inflammatory Syndrome in Adults		80(25.6%)	63(20.1%)	91(29.1%)	53(16.9%)	26(08.3%)		313
Multisystem Inflammatory Syndrome in Children	146(89.0%)	18(11.0%)						164
Myopericarditis	868(19.0%)	2425(53.2%)	593(13.0%)	285(06.3%)	109(02.4%)	20(00.4%)	260(05.7%)	4560
Narcolepsy	2(04.3%)	18(38.3%)	12(25.5%)	7(14.9%)	1(02.1%)	1(02.1%)	6(12.8%)	47
Pregnant	104(01.1%)	7323(80.7%)	421(04.6%)	268(03.0%)	103(01.1%)	32(00.4%)	820(09.0%)	9071
Seizure	755(11.7%)	3559(55.3%)	954(14.8%)	510(07.9%)	278(04.3%)	125(01.9%)	254(03.9%)	6435
Stroke	32(00.7%)	741(15.5%)	1206(25.2%)	1112(23.3%)	847(17.7%)	457(09.6%)	385(08.1%)	4780
Transverse Myelitis	4(01.5%)	106(40.0%)	68(25.7%)	35(13.2%)	20(07.5%)	5(01.9%)	27(10.2%)	265
V-safe Serious	22(01.2%)	619(33.0%)	600(31.9%)	452(24.1%)	147(07.8%)	30(01.6%)	8(00.4%)	1878

VAERS Pre-specified Conditions for COVID19 Reports, Automated Data (non-reviewed)
Initial domestic reports only, VAERS reports as of 04/15/2022 at 3PM

1

Condition	Age group							Total
	0-17	18-49	50-64	65-74	75-84	85+	UNK	
Acute Myocardial Infarction	20(00.6%)	679(20.4%)	809(24.3%)	774(23.2%)	529(15.9%)	304(09.1%)	216(06.5%)	3331
Anaphylaxis	83(03.1%)	1436(53.5%)	663(24.7%)	213(07.9%)	65(02.4%)	11(00.4%)	212(07.9%)	2683
Appendicitis	81(09.3%)	470(53.9%)	188(21.6%)	79(09.1%)	19(02.2%)	3(00.3%)	32(03.7%)	872
Bells Palsy	138(02.2%)	2440(39.5%)	1738(28.1%)	944(15.3%)	418(06.8%)	200(03.2%)	299(04.8%)	6177
COVID19								.
Coagulopathy	154(01.3%)	3656(30.4%)	3154(26.2%)	2304(19.2%)	1265(10.5%)	497(04.1%)	998(08.3%)	12028
Death	70(00.5%)	1032(07.3%)	2186(15.6%)	3185(22.7%)	3461(24.6%)	2946(21.0%)	1169(08.3%)	14049
Guillian-Barre Syndrome	30(02.7%)	371(33.6%)	329(29.8%)	174(15.8%)	86(07.8%)	16(01.4%)	98(08.9%)	1104
Kawasaki Disease	12(80.0%)	2(13.3%)		1(06.7%)				15
Multisystem Inflammatory Syndrome in Adults		80(25.1%)	65(20.4%)	94(29.5%)	54(16.9%)	26(08.2%)		319
Multisystem Inflammatory Syndrome in Children	155(89.6%)	18(10.4%)						173
Myopericarditis	877(19.0%)	2448(53.1%)	600(13.0%)	290(06.3%)	110(02.4%)	20(00.4%)	266(05.8%)	4611
Narcolepsy	2(04.3%)	17(37.0%)	12(26.1%)	7(15.2%)	1(02.2%)	1(02.2%)	6(13.0%)	46
Pregnant	107(01.2%)	7386(80.7%)	426(04.7%)	269(02.9%)	103(01.1%)	32(00.3%)	824(09.0%)	9147
Seizure	752(11.6%)	3563(55.2%)	965(14.9%)	515(08.0%)	283(04.4%)	125(01.9%)	257(04.0%)	6460
Stroke	32(00.7%)	754(15.6%)	1217(25.2%)	1119(23.2%)	856(17.7%)	462(09.6%)	386(08.0%)	4826
Transverse Myelitis	4(01.5%)	108(40.3%)	69(25.7%)	35(13.1%)	20(07.5%)	5(01.9%)	27(10.1%)	268
V-safe Serious	23(01.2%)	633(32.6%)	634(32.6%)	469(24.1%)	146(07.5%)	30(01.5%)	8(00.4%)	1943

**Primary Domestic VAERS COVID-19 Reports by Jurisdiction and Severity
Vaccinated and Received: December 14, 2020 - 04/15/2022 or missing
VAERS reports as of 04/15/2022 at 3PM
(N=807950)**

1

Jurisdiction	Estimated Population ^{1,2}	Death Reports ⁴ N(%)	Non-Death Serious Reports ⁵ N(%)	Non-Serious Reports N(%)	All Reports N
Alaska	731,545	34 (1.4)	104 (4.4)	2,236 (94.2)	2374
Alabama	4,903,185	84 (1.2)	422 (5.9)	6,613 (92.9)	7119
Arkansas	3,017,804	105 (2.2)	584 (12.3)	4,053 (85.5)	4742
Arizona	7,278,717	133 (0.8)	1,016 (6.1)	15,630 (93.2)	16779
California	39,512,223	645 (0.8)	4,796 (6.2)	71,955 (93.0)	77396
Colorado	5,758,736	118 (0.8)	1,184 (8.1)	13,380 (91.1)	14682
Connecticut	3,565,287	70 (0.7)	635 (6.1)	9,638 (93.2)	10343
District of Columbia	705,749	18 (0.9)	118 (5.9)	1,867 (93.2)	2003
Delaware	973,764	22 (1.0)	161 (7.4)	2,002 (91.6)	2185
Florida	21,477,737	520 (1.2)	4,244 (9.5)	39,907 (89.3)	44671
Georgia	10,617,423	342 (1.9)	1,437 (7.8)	16,694 (90.4)	18473
Hawaii	1,415,872	42 (1.4)	200 (6.6)	2,768 (92.0)	3010
Iowa	3,155,070	103 (1.7)	563 (9.4)	5,292 (88.8)	5958
Idaho	1,787,065	29 (0.8)	235 (6.4)	3,384 (92.8)	3648
Illinois	12,671,821	341 (1.3)	2,178 (8.6)	22,799 (90.1)	25318
Indiana	6,732,219	159 (0.6)	827 (3.1)	25,635 (96.3)	26621
Kansas	2,913,314	81 (1.4)	399 (6.9)	5,321 (91.7)	5801
Kentucky	4,467,673	742 (6.4)	1,899 (16.3)	9,012 (77.3)	11653
Louisiana	4,648,794	77 (1.2)	429 (6.8)	5,843 (92.0)	6349
Massachusetts	6,892,503	148 (0.8)	1,259 (7.0)	16,680 (92.2)	18087
Maryland	6,045,680	135 (0.9)	1,215 (7.9)	13,984 (91.2)	15334
Maine	1,344,212	39 (1.0)	240 (6.1)	3,667 (92.9)	3946
Michigan	9,986,857	654 (2.4)	5,857 (21.5)	20,702 (76.1)	27213
Minnesota	5,639,632	455 (2.5)	3,348 (18.7)	14,105 (78.8)	17908
Missouri	6,137,428	260 (2.1)	1,240 (10.0)	10,960 (88.0)	12460

¹ Source for Estimated State Data: <https://www.census.gov/data/tables/time-series/demo/popest/2010s-state-total.html>

² Source for 2018 Estimated Freely Associated States and Guam Data: <https://sdd.spc.int/>

³ Source for 2020 Estimated US Virgin Islands Data: <https://www.worldometers.info/world-population/united-states-virgin-islands-population/>

⁴ Death Reports include unconfirmed reports of death. Some cases are pending confirmation by autopsy, medical record, or death certificate (VAERS form Item 21)

⁵ Non-Death Serious reports include reports of life-threatening conditions, hospitalization, extended hospitalization, permanent disability, or birth defect (VAERS form Item 21)

PSICOVID_00000043

**Primary Domestic VAERS COVID-19 Reports by Jurisdiction and Severity
Vaccinated and Received: December 14, 2020 - 04/15/2022 or missing
VAERS reports as of 04/15/2022 at 3PM
(N=807950)**

Jurisdiction	Estimated Population^{1,2}	Death Reports⁴ N(%)	Non-Death Serious Reports⁵ N(%)	Non-Serious Reports N(%)	All Reports N
Mississippi	2,976,149	63 (1.8)	199 (5.7)	3,205 (92.4)	3467
Montana	1,068,778	113 (3.6)	532 (16.7)	2,538 (79.7)	3183
North Carolina	10,488,084	168 (0.8)	1,466 (7.4)	18,260 (91.8)	19894
North Dakota	762,062	39 (2.3)	294 (17.3)	1,364 (80.4)	1697
Nebraska	1,934,408	58 (1.6)	280 (7.8)	3,240 (90.6)	3578
New Hampshire	1,359,711	84 (2.1)	290 (7.4)	3,571 (90.5)	3945
New Jersey	8,882,190	199 (0.9)	1,748 (7.6)	21,155 (91.6)	23102
New Mexico	2,096,829	51 (1.1)	239 (5.2)	4,340 (93.7)	4630
Nevada	3,080,156	44 (0.8)	427 (8.0)	4,835 (91.1)	5306
New York	19,453,561	378 (0.9)	3,065 (7.2)	39,419 (92.0)	42862
Ohio	11,689,100	332 (1.4)	2,061 (8.8)	21,095 (89.8)	23488
Oklahoma	3,956,971	138 (1.8)	608 (7.8)	7,054 (90.4)	7800
Oregon	4,217,737	85 (0.8)	738 (6.9)	9,800 (92.3)	10623
Pennsylvania	12,801,989	288 (1.0)	2,034 (7.2)	25,819 (91.7)	28141
Rhode Island	1,059,361	21 (0.8)	163 (6.4)	2,373 (92.8)	2557
South Carolina	5,148,714	74 (0.9)	566 (7.0)	7,410 (92.0)	8050
South Dakota	884,659	164 (9.8)	108 (6.5)	1,395 (83.7)	1667
Tennessee	6,829,174	895 (7.3)	954 (7.8)	10,366 (84.9)	12215
Texas	28,995,881	731 (1.6)	2,885 (6.5)	40,847 (91.9)	44463
Utah	3,205,958	38 (0.7)	357 (6.5)	5,080 (92.8)	5475
Virginia	8,535,519	161 (0.9)	1,272 (6.9)	17,054 (92.2)	18487
Vermont	623,989	15 (0.7)	108 (5.2)	1,949 (94.1)	2072
Washington	7,614,893	210 (1.1)	1,473 (7.7)	17,384 (91.2)	19067
Wisconsin	5,822,434	407 (2.9)	1,385 (9.8)	12,360 (87.3)	14152
West Virginia	1,792,147	67 (2.2)	294 (9.7)	2,683 (88.1)	3044

¹ Source for Estimated State Data: <https://www.census.gov/data/tables/time-series/demo/popest/2010s-state-total.html>

² Source for 2018 Estimated Freely Associated States and Guam Data: <https://sdd.spc.int/>

³ Source for 2020 Estimated US Virgin Islands Data: <https://www.worldometers.info/world-population/united-states-virgin-islands-population/>

⁴ Death Reports include unconfirmed reports of death. Some cases are pending confirmation by autopsy, medical record, or death certificate (VAERS form Item 21)

⁵ Non-Death Serious reports include reports of life-threatening conditions, hospitalization, extended hospitalization, permanent disability, or birth defect (VAERS form Item 21)

Primary Domestic VAERS COVID-19 Reports by Jurisdiction and Severity
Vaccinated and Received: December 14, 2020 - 04/15/2022 or missing
VAERS reports as of 04/15/2022 at 3PM
(N=807950)

Jurisdiction	Estimated Population¹²³	Death Reports⁴ N(%)	Non-Death Serious Reports⁵ N(%)	Non-Serious Reports N(%)	All Reports N
Wyoming	578,759	24 (2.4)	76 (7.7)	890 (89.9)	990
Not Specified	NA	2,807 (2.7)	10,067 (9.6)	92,410 (87.8)	105284
United States	328,239,523	13,010 (1.6)	68,279 (8.5)	722,023 (89.9)	803312
American Samoa	56,700	1 (3.0)	2 (6.1)	30 (90.9)	33
Federated States of Micronesia	105,300		2 (40.0)	3 (60.0)	5
Guam	172,400	4 (2.4)	15 (9.0)	148 (88.6)	167
Republic of the Marshall Islands	55,500		1 (16.7)	5 (83.3)	6
Commonwealth of the Northern Mariana Islands	56,200	11 (28.2)	5 (12.8)	23 (59.0)	39
Puerto Rico	3,193,694	118 (2.8)	160 (3.7)	4,006 (93.5)	4284
Republic of Palau	17,900			2 (100.0)	2
QM	NA			2 (100.0)	2
QW	NA			1 (100.0)	1
Tx	NA			1 (100.0)	1
U.S. Virgin Islands	104,433		5 (5.3)	89 (94.7)	94
XB	NA		1 (50.0)	1 (50.0)	2
XV	NA		1 (50.0)	1 (50.0)	2

¹ Source for Estimated State Data: <https://www.census.gov/data/tables/time-series/demo/popest/2010s-state-total.html>

² Source for 2018 Estimated Freely Associated States and Guam Data: <https://sdd.spc.int/>

³ Source for 2020 Estimated US Virgin Islands Data: <https://www.worldometers.info/world-population/united-states-virgin-islands-population/>

⁴ Death Reports include unconfirmed reports of death. Some cases are pending confirmation by autopsy, medical record, or death certificate (VAERS form Item 21)

⁵ Non-Death Serious reports include reports of life-threatening conditions, hospitalization, extended hospitalization, permanent disability, or birth defect (VAERS form Item 21)

PREFERRED Medical Dictionary for Regulatory Activities (MedDRA) Terms (VAERS-1 Box 7, VAERS 2.0 Box 18)

For Current Week and Past Week Comparison

Following **ALL 12/14/2020-04/15/2022 COVID19 MODERNA Ages 18+ Vaccines**

Compared to **ALL 12/14/2020-04/15/2022 COVID19 PFIZER Ages 18+ Vaccines**

AGES 18+ YEARS, Initial domestic reports only, VAERS reports as of 04/15/2022

Vaccination, Received, and Completed Date: 12/14 - 04/15 (Current Week) and 12/14 - 04/08 (Past Week)

N>=3 (Current Week), PRR>=2.00 (Ratio of Proportions), Chi-Square>=4.00

MedDRA PTs sorting based on lower confidence limit and MODERNA adverse event count from 12/14/2020-04/15/2022

AGES 18+ YEARS excludes missing ages

MedDRA Codes ALL Reports (18+)	12/14/2020- 04/15/2022 MODERNA N=323433	12/14/2020- 04/15/2022 PFIZER N=303122	12/14-04/15 Chi-Square	12/14-04/15 PRR	12/14-04/15 LCL	12/14-04/15 UCL	12/14/2020- 04/08/2022 MODERNA N=322944	12/14/2020- 04/08/2022 PFIZER N=302401	12/14-04/08 Chi-Square	12/14-04/08 PRR	12/14-04/08 LCL	12/14-04/08 UCL
PRODUCT DOSE OMISSION ISSUE	1627	71	1330.01	21.48	16.93	37.24	1627	70	1331.36	21.76	17.13	27.65
MECHANICAL URTICARIA	755	56	557.65	12.64	9.63	16.58	744	55	549.37	12.67	9.63	16.66
ACCIDENTAL OVERDOSE	277	20	204.69	12.98	8.25	20.43	277	20	204.48	12.97	8.24	20.42
VACCINATION SITE INDURATION	1083	103	748.10	9.85	8.05	12.06	1083	101	751.86	10.04	8.19	12.31
INTENTIONAL PRODUCT USE ISSUE	132	9	97.92	13.75	7.00	27.00	132	9	97.82	13.73	6.99	26.98
INJECTION SITE RASH	10232	1390	6287.59	6.90	6.52	7.29	10238	1386	6294.21	6.92	6.54	7.31
INJECTION SITE PRURITUS	18120	2587	11041.19	6.56	6.30	6.84	18133	2582	11051.13	6.58	6.31	6.85
INJECTION SITE INDURATION	5062	731	2992.62	6.49	6.01	7.01	5066	728	2998.68	6.52	6.03	7.04
INJECTION SITE WARMTH	13092	2093	7456.77	5.86	5.60	6.14	13098	2086	7466.98	5.88	5.62	6.16
DEVICE CONNECTION ISSUE	301	42	177.98	6.72	4.86	9.28	301	42	177.77	6.71	4.86	9.27
INJECTION SITE ERYTHEMA	25277	4759	13370.46	4.98	4.83	5.13	25290	4746	13389.90	4.99	4.84	5.14
TYPE IV HYPERSENSITIVITY REACTION	117	13	75.16	8.43	4.76	14.96	117	13	75.08	8.43	4.75	14.95
INTENTIONAL DOSE OMISSION	84	9	54.25	8.75	4.40	17.39	84	9	54.19	8.74	4.39	17.38
PRODUCT LABEL CONFUSION	44	3	31.53	13.75	4.27	44.27	44	3	31.50	13.73	4.26	44.23
VACCINATION SITE WARMTH	2713	553	1298.80	4.60	4.20	5.04	2711	553	1295.40	4.59	4.19	5.03
VACCINATION SITE PRURITUS	3264	676	1546.38	4.53	4.17	4.92	3264	675	1545.98	4.53	4.17	4.92
VACCINATION SITE RASH	2068	434	967.45	4.47	4.03	4.95	2067	433	966.99	4.47	4.03	4.96
VACCINATION SITE REACTION	1047	210	504.66	4.67	4.03	5.42	1048	210	504.82	4.67	4.03	5.42
INJECTION SITE REACTION	4035	882	1837.71	4.29	3.99	4.61	4031	875	1843.39	4.31	4.01	4.64
INJECTION SITE URTICARIA	1272	263	596.93	4.50	3.94	5.13	1276	263	602.76	4.54	3.98	5.19
INJECTION SITE INFLAMMATION	873	182	408.77	4.50	3.83	5.27	873	179	413.26	4.57	3.89	5.26
INJECTION SITE HYPERSENSITIVITY	151	24	82.85	5.90	3.83	9.07	151	23	84.65	6.15	3.96	9.53
VACCINATION SITE LYMPHADENOPATHY	155	26	82.52	5.59	3.69	8.46	154	26	81.57	5.55	3.66	8.40
INJECTION SITE SWELLING	19606	4891	8240.16	3.76	3.64	3.87	19614	4884	8245.86	3.76	3.65	3.88
INJECTION SITE PAPULE	53	6	32.98	8.28	3.56	19.26	53	6	32.94	8.27	3.56	19.24
INDURATION	1712	408	721.80	3.93	3.53	4.38	1713	406	724.64	3.95	3.55	4.40
INJECTION SITE CELLULITIS	329	69	152.43	4.47	3.45	5.79	330	68	154.71	4.54	3.50	5.90
EXPIRED PRODUCT ADMINISTERED	11532	3041	4520.80	3.55	3.42	3.70	11398	2979	4499.53	3.58	3.44	3.73
INJECTION SITE IRRITATION	260	53	122.74	4.60	3.42	6.18	260	53	122.58	4.59	3.42	6.17
VACCINATION SITE ERYTHEMA	4869	1261	1915.74	3.62	3.40	3.85	4869	1258	1917.26	3.62	3.41	3.86
PRODUCT ADMINISTRATION INTERRUPTED	31	3	19.75	9.68	2.96	31.68	31	3	19.73	9.68	2.96	31.65
INJECTION SITE MASS	2307	688	776.87	3.14	2.89	3.42	2305	685	778.05	3.15	2.89	3.43
LOCAL REACTION	233	57	94.71	3.83	2.87	5.12	233	56	96.08	3.90	2.91	5.22

SKIN WARM	6808	2190	2111.68	2.91	2.78	3.06	6803	2190	2104.43	2.91	2.77	3.05
VACCINATION SITE URTICARIA	252	67	94.69	3.52	2.69	4.61	252	67	94.54	3.52	2.69	4.61
INJECTION SITE NODULE	898	275	291.58	3.06	2.67	3.50	898	271	296.23	3.10	2.71	3.55
POOR QUALITY PRODUCT ADMINISTERED	693	211	226.26	3.08	2.64	3.59	712	165	305.76	4.04	3.41	4.79
SKIN INDURATION	162	41	63.46	3.70	2.63	5.22	160	41	61.82	3.65	2.59	5.15
VACCINATION COMPLICATION	2659	886	779.82	2.81	2.61	3.03	2662	887	779.28	2.81	2.61	3.03
SKIN REACTION	552	170	177.50	3.04	2.56	3.61	552	169	178.47	3.06	2.57	3.63
MATERNAL EXPOSURE DURING PREGNANCY	720	229	222.80	2.95	2.54	3.42	720	227	224.89	2.97	2.56	3.45
VACCINATION SITE DISCOLOURATION	258	74	89.50	3.27	2.52	4.23	258	73	90.70	3.31	2.55	4.29
INJECTION SITE OEDEMA	175	48	63.35	3.42	2.48	4.70	173	47	63.14	3.45	2.50	4.76
INJECTION SITE INDENTATION	100	25	39.19	3.75	2.42	5.81	100	25	39.13	3.75	2.42	5.81
VACCINATION SITE MOVEMENT IMPAIRMENT	266	81	86.14	3.08	2.40	3.95	266	81	85.99	3.08	2.40	3.94
VACCINATION SITE SWELLING	3749	1423	908.31	2.47	2.32	2.62	3748	1421	907.91	2.47	2.32	2.62
INJECTION SITE DISCOLOURATION	472	160	133.83	2.76	2.31	3.31	472	160	133.57	2.76	2.31	3.30
VACCINATION SITE DISCHARGE	41	8	18.90	4.80	2.25	10.25	41	8	18.87	4.80	2.25	10.24
CHRONIC SPONTANEOUS URTICARIA	116	33	40.02	3.29	2.24	4.85	113	33	37.76	3.21	2.18	4.73
CELLULITIS	1180	445	286.71	2.49	2.23	2.77	1177	443	286.30	2.49	2.23	2.77
POST-ACUTE COVID-19 SYNDROME	227	74	67.32	2.87	2.21	3.74	228	71	71.58	3.01	2.30	3.92
RASH ERYTHEMATOUS	7304	3033	1524.60	2.26	2.16	2.35	7294	3030	1518.01	2.25	2.16	2.35
PRODUCT AVAILABILITY ISSUE	26	4	13.38	6.09	2.13	17.45	26	4	13.37	6.09	2.12	17.44
INJECTION SITE STREAKING	47	11	18.93	4.00	2.08	7.72	47	11	18.91	4.00	2.08	7.71
EXPOSURE VIA SKIN CONTACT	119	38	35.79	2.93	2.04	4.23	119	38	35.73	2.93	2.04	4.22
ERYTHEMA	15831	7161	2837.72	2.07	2.02	2.13	15826	7154	2834.00	2.07	2.02	2.13
EXPOSURE VIA BREAST MILK	54	14	19.93	3.61	2.01	6.51	54	14	19.90	3.61	2.01	6.50
SKIN SWELLING	488	200	102.06	2.29	1.94	2.70	489	197	105.29	2.32	1.97	2.74
INJECTION SITE INFECTION	106	35	30.40	2.84	1.94	4.16	106	35	30.34	2.84	1.94	4.16
INJECTION SITE ABSCESS	81	25	25.11	3.04	1.94	4.75	81	25	25.07	3.03	1.94	4.75
VACCINATION SITE CELLULITIS	45	13	14.64	3.24	1.75	6.01	45	13	14.61	3.24	1.75	6.01
ERYTHEMA MULTIFORME	130	51	28.78	2.39	1.73	3.30	129	50	29.10	2.42	1.74	3.35
ANTIBODY TEST NEGATIVE	24	5	10.05	4.50	1.72	11.79	24	5	10.03	4.49	1.71	11.78
VACCINATION SITE INFLAMMATION	160	66	32.52	2.27	1.71	3.03	160	65	33.39	2.30	1.73	3.07
SKIN INFECTION	64	24	14.87	2.50	1.56	4.00	66	24	16.10	2.58	1.61	4.11
INJECTION SITE MACULE	22	5	8.48	4.12	1.56	10.89	22	5	8.47	4.12	1.56	10.88
TOOTH LOSS	22	5	8.48	4.12	1.56	10.89	22	5	8.47	4.12	1.56	10.88
URTICARIA CHRONIC	117	52	20.29	2.11	1.52	2.92	117	52	20.24	2.11	1.52	2.92
INJECTION SITE PUSTULE	37	12	10.26	2.89	1.51	5.54	37	12	10.24	2.89	1.51	5.54
INJECTION SITE EXTRAVASATION	91	39	16.86	2.19	1.50	3.18	91	39	16.82	2.18	1.50	3.18
LYMPHADENOPATHY	84	37	14.65	2.13	1.45	3.13	84	37	14.61	2.13	1.44	3.13
INJECTION SITE SCAR	38	14	8.75	2.54	1.38	4.69	38	14	8.73	2.54	1.38	4.69
INJECTION SITE SCAB	57	25	9.81	2.14	1.34	3.42	57	25	9.78	2.13	1.33	3.42
VACCINATION SITE SCAR	25	8	6.76	2.93	1.32	6.49	25	8	6.75	2.93	1.32	6.49
DENTAL DISCOMFORT	39	16	7.44	2.28	1.28	4.09	39	16	7.42	2.28	1.28	4.08
MYOSCLEROSIS	37	15	7.18	2.31	1.27	4.21	38	15	7.75	2.37	1.30	4.31
MULTIPLE USE OF SINGLE-USE PRODUCT	14	3	5.26	4.37	1.26	15.22	14	3	5.25	4.37	1.26	15.21
LEMB IMMOBILISATION	32	13	6.09	2.31	1.21	4.40	32	13	6.07	2.30	1.21	4.39

FEELING OF RELAXATION	26	10	5.32	2.44	1.38	5.05	26	10	5.31	2.43	1.17	5.05
PRODUCT COLOUR ISSUE	13	3	4.50	4.06	1.16	14.25	13	3	4.49	4.06	1.16	14.24
INJECTION RELATED REACTION	20	7	4.59	2.68	1.13	6.33	20	7	4.58	2.68	1.13	6.33
LEFT VENTRICULAR ENLARGEMENT	18	6	4.36	2.81	1.12	7.08	18	6	4.35	2.81	1.12	7.08
GINGIVITIS	21	8	4.22	2.46	1.09	5.55	21	8	4.21	2.46	1.09	5.55
VACCINATION SITE NODULE	84	39	13.03	2.02	1.38	2.95	83	39	12.48	1.99	1.36	2.92
ACCIDENTAL UNDERDOSE	201	2	180.75	94.19	23.40	379.20	201	2	180.59	94.11	23.37	378.87
VACCINATION SITE DYSAESTHESIA	20	1	14.30	18.74	2.52	139.66	20	1	14.28	18.73	2.51	139.54
PRODUCT CONTAMINATION PHYSICAL	19	1	13.38	17.81	2.38	133.01	19	1	13.37	17.79	2.38	132.90
VACCINATION SITE ANAESTHESIA	19	1	13.38	17.81	2.38	133.01	19	1	13.37	17.79	2.38	132.90
VACCINATION SITE HYPERSENSITIVITY	16	2	8.57	7.50	1.72	32.61	16	2	8.56	7.49	1.72	32.58
PRODUCT EXPIRATION DATE ISSUE	13	2	6.04	6.09	1.37	26.99	13	2	6.03	6.09	1.37	26.97
VACCINATION SITE STREAKING	11	2	4.42	5.15	1.14	23.25	11	2	4.42	5.15	1.14	23.23
CHALAZION	15	5	3.49	2.81	1.02	7.74	15	4	4.63	3.51	1.17	10.58
SOFT TISSUE NECROSIS	5	1	1.31	4.69	0.55	40.11	5	0				

PREFERRED Medical Dictionary for Regulatory Activities (MedDRA) Terms (VAERS-1 Box 7, VAERS 2.0 Box 18)

For Current Week and Past Week Comparison

Following **ALL 12/14/2020-04/15/2022 COVID19 MODERNA Ages 18+ Vaccines**

Compared to **ALL 12/14/2020-04/15/2022 COVID19 PFIZER Ages 18+ Vaccines**

SERIOUS AGES 18+ YEARS, Initial domestic reports only, VAERS reports as of 04/15/2022

Vaccination, Received, and Completed Date: 12/14 - 04/15 (Current Week) and 12/14 - 04/08 (Past Week)

N $\geq$ 3 (Current Week), PRR $\geq$ 2.00 (Ratio of Proportions), Chi-Square $\geq$ 4.00

MedDRA PTs sorting based on lower confidence limit and MODERNA adverse event count from 12/14/2020-04/15/2022

SERIOUS AGES 18+ YEARS excludes missing ages

MedDRA Codes ALL Reports (SERIOUS 18+)	12/14/2020- 04/15/2022 MODERNA N=30088	12/14/2020- 04/15/2022 PFIZER N=36782	12/14-04/15 Chi-Square	12/14-04/15 PRR	12/14-04/15 LCL	12/14-04/15 UCL	12/14/2020- 04/08/2022 MODERNA N=29929	12/14/2020- 04/08/2022 PFIZER N=36603	12/14-04/08 Chi-Square	12/14-04/08 PRR	12/14-04/08 LCL	12/14-04/08 UCL
PRODUCT DOSE OMISSION												
ISSUE	127	18	104.79	8.63	5.27	14.13	127	18	104.85	8.63	5.27	14.13
MECHANICAL URTICARIA	20	3	14.72	8.15	2.42	27.42	21	3	15.86	8.56	2.55	28.70
INJECTION SITE ERYTHEMA	136	54	53.34	3.08	2.25	4.22	133	55	49.51	2.96	2.16	4.05
VACCINATION SITE ERYTHEMA	35	12	15.34	3.57	1.85	6.87	35	12	15.35	3.57	1.85	6.87
INJECTION SITE SWELLING	143	75	36.68	2.33	1.76	3.08	140	75	34.51	2.28	1.73	3.02
INJECTION SITE PRURITUS	63	28	20.66	2.75	1.76	4.29	62	28	19.85	2.71	1.73	4.23
INCOMPLETE COURSE OF VACCINATION	99	56	21.61	2.16	1.56	3.00	99	56	21.63	2.16	1.56	3.00
INJECTION SITE WARMTH	53	26	14.72	2.49	1.56	3.98	52	26	13.97	2.45	1.53	3.92
INJECTION SITE REACTION	46	22	13.21	2.56	1.54	4.35	46	22	13.22	2.56	1.54	4.25
DRUG REACTION WITH EOSINOPHILIA AND SYSTEMIC SYMPTOMS	17	5	8.01	4.16	1.53	11.26	17	5	8.01	4.16	1.53	11.27
OPTIC ISCHAEMIC NEUROPATHY	20	7	8.09	3.49	1.48	8.26	20	7	8.10	3.49	1.48	8.26
GRANULOMA	14	4	6.55	4.28	1.41	13.00	14	4	6.55	4.28	1.41	13.00
VACCINATION SITE RASH	14	4	6.55	4.28	1.41	13.00	14	4	6.55	4.28	1.41	13.00
VACCINATION SITE REACTION	14	4	6.55	4.28	1.41	13.00	14	4	6.55	4.28	1.41	13.00
VENA CAVA THROMBOSIS	12	3	6.08	4.89	1.38	17.33	12	3	6.09	4.89	1.38	17.33
VACCINATION SITE WARMTH	17	6	6.65	3.46	1.37	8.78	17	6	6.65	3.47	1.37	8.79
SUDDEN CARDIAC DEATH	42	23	9.34	2.23	1.34	3.71	42	23	9.35	2.23	1.34	3.71
INJECTION SITE INDURATION	26	12	7.51	2.65	1.34	5.25	27	13	7.31	2.54	1.31	4.92
CHOLECYSTITIS INFECTIVE	16	6	5.76	3.26	1.28	8.33	16	6	5.77	3.26	1.28	8.33
RASH PAPULAR	40	23	7.99	2.13	1.27	3.55	40	22	8.79	2.22	1.32	3.74
CARDIAC DISCOMFORT	21	10	5.60	2.57	1.21	5.45	21	10	5.60	2.57	1.21	5.45
FACET JOINT SYNDROME	15	6	4.91	3.06	1.19	7.88	15	6	4.91	3.06	1.19	7.88
DISSOCIATION	12	4	4.67	3.67	1.18	11.37	12	4	4.68	3.67	1.18	11.37
LEFT VENTRICULAR ENLARGEMENT	12	4	4.67	3.67	1.18	11.37	12	4	4.68	3.67	1.18	11.37
IMPAIRED HEALING	24	13	5.13	2.26	1.15	4.43	24	13	5.14	2.26	1.15	4.43
B-CELL LYMPHOMA	13	5	4.35	3.18	1.13	8.91	12	4	4.68	3.67	1.18	11.37
ECTOPIC PREGNANCY	10	3	4.14	4.07	1.12	14.81	10	3	4.15	4.08	1.12	14.81
NERVE BLOCK	10	3	4.14	4.07	1.12	14.81	10	3	4.15	4.08	1.12	14.81
TOBACCO USER	27	16	4.81	2.06	1.11	3.83	27	16	4.82	2.06	1.11	3.83
MYOCARDIAL FIBROSIS	28	17	4.73	2.01	1.10	3.68	28	17	4.73	2.01	1.10	3.68
RIGHT VENTRICULAR FAILURE	25	15	4.27	2.04	1.07	3.86	25	15	4.28	2.04	1.07	3.87
SLEEP DEFICIT	13	2	8.91	7.95	1.79	35.21	13	2	8.92	7.95	1.79	35.22
VACCINATION SITE INDURATION	12	2	7.81	7.33	1.64	32.77	12	2	7.81	7.34	1.64	32.78
INTENTIONAL DOSE OMISSION	11	2	6.72	6.72	1.49	30.33	11	2	6.73	6.73	1.49	30.34
CHRONIC SPONTANEOUS URTICARIA	10	2	5.66	6.11	1.34	27.89	10	2	5.67	6.11	1.34	27.91

PREFERRED Medical Dictionary for Regulatory Activities (MedDRA) Terms (VAERS-1 Box 7, VAERS 2.0 Box 18)

For Current Week and Past Week Comparison

Following **ALL 12/14/2020-04/15/2022 COVID19 MODERNA Ages 18+ Vaccines**Compared to **ALL 12/14/2020-04/15/2022 COVID19 PFIZER Ages 18+ Vaccines****NON-SERIOUS AGES 18+ YEARS**, Initial domestic reports only, VAERS reports as of 04/15/2022

Vaccination, Received, and Completed Date: 12/14 - 04/15 (Current Week) and 12/14 - 04/08 (Past Week)

N $\geq$ 3 (Current Week), PRR $\geq$ 2.00 (Ratio of Proportions), Chi-Square $\geq$ 4.00

MedDRA PTs sorting based on lower confidence limit and MODERNA adverse event count from 12/14/2020-04/15/2022

NON-SERIOUS AGES 18+ YEARS excludes missing ages

MedDRA Codes ALL Reports (NON-SERIOUS 18+)	12/14/2020- 04/15/2022 MODERNA N=293345	12/14/2020- 04/15/2022 PFIZER N=266340	12/14-04/15 Chi-Square	12/14-04/15 PRR	12/14-04/15 LCL	12/14-04/15 UCL	12/14/2020- 04/08/2022 MODERNA N=293015	12/14/2020- 04/08/2022 PFIZER N=265798	12/14-04/08 Chi-Square	12/14-04/08 PRR	12/14-04/08 LCL	12/14-04/08 UCL
PRODUCT DOSE OMISSION												
ISSUE	1500	53	1216.65	25.70	19.54	33.79	1500	52	1218.10	26.17	19.85	34.50
ACCIDENTAL OVERDOSE	270	12	210.67	20.43	11.46	36.42	270	12	210.46	20.41	11.45	36.39
MECHANICAL URTICARIA	735	53	526.61	12.59	9.53	16.64	723	52	517.74	12.61	9.52	16.71
VACCINATION SITE INDURATION	1071	101	713.53	9.63	7.85	11.81	1071	99	717.24	9.81	7.99	12.06
INJECTION SITE RASH	10182	1355	6066.06	6.82	6.45	7.22	10188	1351	6072.33	6.84	6.46	7.34
INTENTIONAL PRODUCT USE ISSUE	124	9	87.25	12.51	6.36	24.61	124	9	87.15	12.50	6.35	24.59
INJECTION SITE PRURITUS	18057	2559	10616.45	6.41	6.15	6.68	18071	2554	10626.55	6.42	6.16	6.69
INJECTION SITE INDURATION	5036	719	2869.84	6.36	5.88	6.88	5039	715	2876.81	6.39	5.91	6.91
INJECTION SITE WARMTH	13039	2067	7153.62	5.73	5.47	6.00	13046	2060	7164.22	5.74	5.49	6.02
TYPE IV HYPERSENSITIVITY REACTION	116	11	75.62	9.57	5.16	17.77	116	11	75.53	9.57	5.15	17.75
DEVICE CONNECTION ISSUE	300	41	171.60	6.64	4.79	9.21	300	41	171.39	6.64	4.79	9.20
INJECTION SITE ERYTHEMA	25141	4705	12799.73	4.85	4.70	5.00	25157	4691	12822.63	4.86	4.72	5.02
INTENTIONAL DOSE OMISSION	73	7	46.84	9.47	4.36	20.56	73	7	46.79	9.46	4.36	20.54
PRODUCT LABEL CONFUSION	44	3	30.37	13.32	4.13	42.88	44	3	30.33	13.30	4.13	42.85
VACCINATION SITE WARMTH	2696	547	1232.99	4.47	4.08	4.91	2694	547	1229.63	4.47	4.08	4.90
VACCINATION SITE PRURITUS	3253	671	1471.43	4.40	4.05	4.78	3253	670	1470.98	4.40	4.05	4.79
INJECTION SITE URTICARIA	1260	253	578.24	4.52	3.95	5.17	1264	251	583.98	4.57	3.99	5.23
VACCINATION SITE REACTION	1033	206	476.00	4.55	3.92	5.29	1034	206	476.12	4.55	3.92	5.29
INJECTION SITE REACTION	3989	860	1746.41	4.21	3.91	4.53	3985	853	1752.06	4.24	3.94	4.56
VACCINATION SITE RASH	2054	430	915.79	4.34	3.91	4.81	2053	429	915.31	4.34	3.91	4.82
INJECTION SITE HYPERSENSITIVITY	149	23	79.39	5.88	3.79	9.12	149	22	81.19	6.14	3.93	9.61
INJECTION SITE INFLAMMATION	867	179	388.98	4.40	3.74	5.16	867	176	393.40	4.47	3.80	5.25
INDURATION	1684	383	701.19	3.99	3.57	4.46	1684	382	701.69	4.00	3.58	4.47
INJECTION SITE SWELLING	19463	4816	7835.54	3.67	3.56	3.79	19474	4809	7843.08	3.67	3.56	3.79
VACCINATION SITE LYMPHADENOPATHY	153	26	77.15	5.34	3.53	8.10	152	26	76.23	5.30	3.50	8.04
INJECTION SITE PAPULE	53	6	31.64	8.02	3.45	18.66	53	6	31.60	8.01	3.44	18.64
VACCINATION COMPLICATION	2204	539	861.47	3.71	3.38	4.08	2206	537	864.61	3.73	3.39	4.09
INJECTION SITE CELLULITIS	323	67	143.46	4.38	3.36	5.69	324	66	145.69	4.45	3.42	5.80
INJECTION SITE IRRITATION	259	52	117.63	4.52	3.36	6.09	259	52	117.47	4.52	3.35	6.09
EXPIRED PRODUCT ADMINISTERED	11525	3039	4279.53	3.44	3.31	3.58	11391	2977	4260.08	3.47	3.33	3.61
VACCINATION SITE ERYTHEMA	4834	1249	1803.69	3.51	3.30	3.74	4834	1246	1805.10	3.52	3.31	3.74
CELLULITIS	985	277	332.31	3.23	2.83	3.69	983	278	328.97	3.21	2.81	3.66
INJECTION SITE MASS	2286	675	732.51	3.07	2.82	3.35	2284	672	733.68	3.08	2.83	3.36

SKIN WARM	6665	2074	2024.47	2.92	2.78	3.06	6662	2075	2017.42	2.91	2.77	3.06
LOCAL REACTION	229	56	88.12	3.71	2.77	4.97	230	55	90.22	3.79	2.83	5.09
PRODUCT ADMINISTRATION	30	3	18.10	9.08	2.77	29.75	30	3	18.07	9.07	2.77	29.72
INTERRUPTED	707	200	236.50	3.21	2.74	3.75	707	199	237.43	3.22	2.75	3.77
MATERNAL EXPOSURE DURING	161	38	63.65	3.85	2.70	5.48	159	38	62.04	3.80	2.66	5.41
PREGNANCY	249	65	89.98	3.48	2.65	4.57	249	65	89.84	3.47	2.64	4.57
VACCINATION SITE URTICARIA	208	53	76.83	3.56	2.64	4.82	209	53	77.44	3.58	2.65	4.84
POST-ACUTE COVID-19	97	21	40.81	4.19	2.62	6.72	97	21	40.75	4.19	2.61	6.72
SYNDROME	889	270	273.79	2.99	2.61	3.43	889	266	278.55	3.03	2.64	3.48
INJECTION SITE INDENTATION	693	209	214.97	3.01	2.58	3.51	712	163	293.05	3.96	3.34	4.70
INJECTION SITE NODULE	540	162	168.32	3.03	2.54	3.61	540	161	169.28	3.04	2.55	3.63
POOR QUALITY PRODUCT	171	45	60.94	3.45	2.48	4.79	170	44	61.51	3.50	2.52	4.88
SKIN REACTION	257	73	84.84	3.20	2.46	4.15	257	72	86.02	3.24	2.49	4.20
INJECTION SITE OEDEMA	262	75	85.75	3.17	2.45	4.10	262	75	85.59	3.17	2.45	4.10
VACCINATION SITE	470	156	128.19	2.74	2.28	3.28	470	156	127.94	2.73	2.28	3.28
DISCOLOURATION	3718	1400	846.96	2.41	2.27	2.56	3718	1398	847.15	2.41	2.27	2.56
VACCINATION SITE MOVEMENT	41	8	17.97	4.65	2.18	9.93	41	8	17.94	4.65	2.18	9.92
IMPAIRMENT	7170	2918	1433.72	2.23	2.14	2.33	7160	2916	1426.36	2.23	2.13	2.32
INJECTION SITE	52	12	20.20	3.93	2.10	7.37	52	12	20.17	3.93	2.10	7.36
DISCOLOURATION	23	3	12.14	6.96	2.09	23.18	23	3	12.12	6.95	2.09	23.16
PRODUCT AVAILABILITY ISSUE	106	31	33.23	3.16	2.08	4.63	103	31	31.10	3.01	2.02	4.50
CHRONIC SPONTANEOUS	15393	6116	2732.93	2.08	2.02	2.14	15389	6110	2728.98	2.08	2.02	2.14
URTICARIA	125	40	35.13	2.84	1.99	4.05	124	39	35.59	2.88	2.01	4.13
ERYTHEMA	104	32	30.61	2.95	1.99	3.01	104	32	30.55	2.95	1.98	4.38
ERYTHEMA MULTIFORME	46	11	17.17	3.80	1.97	7.33	46	11	17.15	3.79	1.96	7.32
INJECTION SITE INFECTION	477	187	99.79	2.32	1.96	2.74	478	184	103.08	2.36	1.99	2.79
INJECTION SITE STREAKING	118	38	32.83	2.82	1.96	4.06	118	38	32.77	2.82	1.95	4.06
SKIN SWELLING	80	24	24.08	3.03	1.92	4.78	80	24	24.04	3.02	1.92	4.77
EXPOSURE VIA SKIN CONTACT	110	42	23.48	2.38	1.67	3.39	110	42	23.43	2.38	1.67	3.39
INJECTION SITE ABSCESS	24	5	9.53	4.36	1.66	11.42	24	5	9.51	4.35	1.66	11.41
URTICARIA CHRONIC	58	19	15.30	2.77	1.65	4.65	60	19	16.59	2.86	1.71	4.80
ANTIBODY TEST NEGATIVE	155	65	28.00	2.17	1.62	2.89	155	64	28.82	2.20	1.64	2.94
SKIN INFECTION	36	10	11.31	3.27	1.62	6.59	36	10	11.29	3.27	1.62	6.58
VACCINATION SITE	42	13	11.71	2.93	1.57	5.46	42	13	11.69	2.93	1.57	5.46
INFLAMMATION	22	5	8.02	3.99	1.51	10.55	22	5	8.01	3.99	1.51	10.54
INJECTION SITE PUSTULE	91	39	15.43	2.12	1.46	3.08	91	39	15.39	2.12	1.45	3.08
INJECTION SITE MACULE	37	12	9.58	2.80	1.46	5.37	37	12	9.56	2.80	1.46	5.36
EXTRAVASATION	16	3	6.48	4.34	1.41	16.62	15	3	5.71	4.54	1.31	15.67
INJECTION SITE SCAR	82	36	13.13	2.07	1.40	3.06	82	36	13.09	2.07	1.40	3.06
MASS EXCISION	17	4	5.76	3.86	1.30	11.47	17	4	5.75	3.86	1.30	11.46
INJECTION SITE	57	25	8.94	2.07	1.29	3.31	57	25	8.92	2.07	1.29	3.31
LYMPHADENOPATHY	31	11	6.88	2.56	1.29	5.09	31	11	6.86	2.56	1.29	5.09
INJECTION RELATED REACTION	19	5	5.86	3.45	1.29	9.24	19	5	5.85	3.45	1.29	9.23
INJECTION SITE SCAB	25	8	6.31	2.34	1.28	6.29	25	8	6.29	2.33	1.28	6.28
LIMB IMMOBILISATION	21	6	5.99	3.18	1.28	7.87	21	6	5.97	3.17	1.28	7.87
EYE COLOUR CHANGE												
VACCINATION SITE SCAR												
URINE OUTPUT INCREASED												

MYOCLEROSIS	36	14	6.93	2.33	1.26	4.33	36	14	6.91	2.33	1.36	4.32
FEELING OF RELAXATION	26	9	5.87	2.62	1.23	5.60	26	9	5.85	2.62	1.23	5.59
GENERALISED OEDEMA	22	7	5.49	2.85	1.22	6.68	22	6	6.66	3.33	1.35	8.20
PHANTOM LIMB SYNDROME	22	7	5.49	2.85	1.22	6.68	22	7	5.48	2.85	1.32	6.67
GINGIVITIS	20	6	5.32	3.03	1.22	7.54	20	6	5.31	3.02	1.21	7.53
MULTIPLE USE OF SINGLE-USE PRODUCT	14	3	4.97	4.24	1.22	14.74	14	3	4.96	4.23	1.22	14.73
TOOTH LOSS	14	3	4.97	4.24	1.22	14.74	14	3	4.96	4.23	1.22	14.73
DENTAL DISCOMFORT	36	15	6.05	2.18	1.19	3.98	36	15	6.03	2.18	1.19	3.98
EPILEPSY	34	14	5.81	2.20	1.18	4.11	34	14	5.80	2.20	1.18	4.10
SKIN PLAQUE	28	11	5.12	2.31	1.15	4.64	28	11	5.11	2.31	1.15	4.64
ABSCESS LIMB	17	5	4.50	3.09	1.14	8.37	17	5	4.49	3.08	1.14	8.36
ECZEMA NUMMULAR	15	4	4.35	3.40	1.13	10.26	15	4	4.34	3.40	1.13	10.25
SKIN IRRITATION	20	7	4.25	2.59	1.10	6.13	20	7	4.24	2.59	1.10	6.13
VACCINATION SITE NODULE	84	38	12.57	2.01	1.37	2.94	83	38	12.03	1.98	1.35	2.91
ACCIDENTAL UNDERDOSE	201	1	177.79	182.50	25.58	1301.87	201	1	177.62	182.33	25.56	1300.68
VACCINATION SITE DYSAESTHESIA	20	1	13.77	18.16	2.44	135.30	20	1	13.76	18.14	2.43	135.18
PRODUCT CONTAMINATION PHYSICAL	19	1	12.89	17.25	2.31	128.86	19	1	12.87	17.24	2.31	128.74
VACCINATION SITE ANAESTHESIA	19	1	12.89	17.25	2.31	128.86	19	1	12.87	17.24	2.31	128.74
VACCINATION SITE HYPERSENSITIVITY	16	2	8.20	7.26	1.67	31.59	16	2	8.18	7.26	1.67	31.56
PRODUCT EXPIRATION DATE ISSUE	13	2	5.75	5.90	1.33	26.15	13	2	5.74	5.90	1.33	26.13
SARS-COV-2 ANTIBODY TEST	11	1	5.92	9.99	1.29	77.36	9	1	4.25	8.16	1.03	64.44
VACCINATION SITE STREAKING	11	2	4.19	4.99	1.11	22.53	11	2	4.18	4.99	1.11	22.51
OROPHARYNGEAL DISORDER	17	6	3.44	2.57	1.01	6.52	17	4	5.75	3.86	1.30	11.46
CHALAZION	15	5	3.24	2.72	0.99	7.49	15	4	4.34	3.40	1.13	10.25

PREFERRED Medical Dictionary for Regulatory Activities (MedDRA) Terms (VAERS-1 Box 7, VAERS 2.0 Box 18)

For Current Week and Past Week Comparison

Following **ALL 12/14/2020-04/15/2022 COVID19 Pfizer Ages 18+ Vaccines**

Compared to **ALL 12/14/2020-04/15/2022 COVID19 Moderna Ages 18+ Vaccines**

AGES 18+ YEARS, Initial domestic reports only, VAERS reports as of 04/15/2022

Vaccination, Received, and Completed Date: 12/14 - 04/15 (Current Week) and 12/14 - 04/08 (Past Week)

N $\geq$ 3 (Current Week), PRR $\geq$ 2.00 (Ratio of Proportions), Chi-Square $\geq$ 4.00

MedDRA PTs sorting based on lower confidence limit and PFIZER adverse event count from 12/14/2020-04/15/2022

AGES 18+ YEARS excludes missing ages

MedDRA Codes ALL Reports (18+)	12/14/2020- 04/15/2022 PFIZER N=303122	12/14/2020- 04/15/2022 MODERNA N=323433	12/14-04/15 Chi-Square	12/14-04/15 PRR	12/14-04/15 LCL	12/14-04/15 UCL	12/14/2020- 04/08/2022 PFIZER N=302401	12/14/2020- 04/08/2022 MODERNA N=322944	12/14-04/08 Chi-Square	12/14-04/08 PRR	12/14-04/08 LCL	12/14-04/08 UCL
PRODUCT PREPARATION ERROR	560	15	551.63	39.83	23.85	66.52	559	15	551.07	39.80	23.83	66.46
VACCINATION FAILURE	977	54	887.78	19.30	14.68	25.39	973	51	892.40	20.37	15.38	27.00
PRODUCT USE ISSUE	432	27	382.95	17.07	11.57	25.18	432	27	383.32	17.09	11.58	25.21
PRODUCT PREPARATION ISSUE	2105	166	1790.23	13.53	11.55	15.85	2107	167	1791.64	13.47	11.51	15.77
DISEASE RECURRENCE	216	11	197.07	20.95	11.43	38.40	215	11	196.20	20.87	11.39	38.26
IMMUNISATION	2517	215	2101.41	12.49	10.87	14.36	2515	215	2101.47	12.49	10.87	14.36
CIRCUMSTANCE OR INFORMATION CAPABLE OF LEADING TO MEDICATION ERROR	124	17	86.82	7.78	4.69	12.92	124	17	86.92	7.79	4.69	12.93
OFF LABEL USE	973	211	541.30	4.92	4.24	5.71	972	211	541.07	4.92	4.24	5.71
IMMUNODEFICIENCY	481	108	260.20	4.75	3.86	5.85	480	107	261.35	4.79	3.89	5.91
DRUG INEFFECTIVE	1023	267	493.72	4.09	3.57	4.68	1021	266	494.21	4.10	3.58	4.69
APPARENT LIFE THREATENING EVENT	64	10	41.52	6.83	3.51	13.30	64	10	41.57	6.83	3.51	13.31
INCORRECT PRODUCT FORMULATION ADMINISTERED	548	162	234.99	3.61	3.03	4.30	548	162	235.35	3.61	3.03	4.30
MIDDLE INSOMNIA	75	17	39.15	4.71	2.78	7.97	75	17	39.21	4.71	2.78	7.98
OVERDOSE	176	56	69.10	3.35	2.48	4.53	176	56	69.21	3.36	2.48	4.53
WHITE BLOOD CELL COUNT INCREASED	113	37	42.58	3.26	2.25	4.72	112	37	41.83	3.23	2.23	4.69
INTERCHANGE OF VACCINE PRODUCTS	5788	2638	1410.30	2.34	2.24	2.45	5777	2635	1408.73	2.34	2.24	2.45
NEAR DEATH EXPERIENCE	106	35	39.49	3.23	2.21	4.74	106	35	39.55	3.23	2.21	4.74
CROHN'S DISEASE	126	45	42.85	2.99	2.13	4.20	126	45	42.93	2.99	2.13	4.20
ANTINUCLEAR ANTIBODY POSITIVE	30	7	14.56	4.57	2.01	10.41	29	7	13.68	4.42	1.94	10.10
DRUG HYPERSENSITIVITY	181	74	51.28	2.61	1.99	3.42	180	74	50.65	2.60	1.98	3.40
SKIN DISORDER	267	118	67.01	2.41	1.94	3.00	266	118	66.46	2.41	1.94	2.99
EXPOSURE TO SARS-COV-2	1236	622	244.92	2.12	1.93	2.33	1227	617	244.11	2.12	1.93	2.34
POLYMENORRHOEA	462	219	102.62	2.25	1.92	2.64	462	219	102.85	2.25	1.92	2.65
EAR DISORDER	108	42	32.58	2.74	1.92	3.92	108	42	31.54	2.68	1.88	3.82
UTERINE HAEMORRHAGE	64	22	22.32	3.10	1.91	5.04	64	22	22.36	3.11	1.91	5.04
MENSTRUAL DISORDER	1594	830	293.63	2.05	1.88	2.23	1598	829	297.58	2.06	1.89	2.24
CLAUSTROPHOBIA	23	5	11.47	4.91	1.87	12.91	23	5	11.48	4.91	1.87	12.92
INTERMENSTRUAL BLEEDING	866	447	162.06	2.07	1.84	2.32	862	445	161.66	2.07	1.85	2.32
HYPOMENORRHOEA	116	48	31.93	2.58	1.84	3.61	116	48	31.99	2.58	1.84	3.61
PHARYNGEAL INFLAMMATION	17	3	9.32	6.05	1.77	20.63	17	3	9.34	6.05	1.77	20.65
STRIDOR	123	54	30.76	2.43	1.76	3.35	122	54	30.14	2.41	1.75	3.32
BONE DISORDER	40	13	14.51	3.28	1.76	6.14	40	13	14.54	3.29	1.76	6.14
UPPER RESPIRATORY TRACT CONGESTION	101	43	26.44	2.51	1.75	3.58	101	42	27.53	2.57	1.79	3.68

ELCTROCARDIOGRAM ABNORMAL	77	31	21.81	2.65	1.75	4.02	77	29	24.07	2.84	1.85	4.35
VIBRATORY SENSE INCREASED	63	24	19.18	2.80	1.75	4.48	64	34	19.97	2.85	1.78	4.55
APPENDICITIS	407	217	70.30	2.00	1.70	2.36	405	215	70.85	2.01	1.71	2.37
HAEMOGLOBIN DECREASED	71	29	19.60	2.61	1.70	4.02	70	30	17.90	2.49	1.62	3.82
MAST CELL ACTIVATION SYNDROME	49	18	15.47	2.90	1.69	4.99	49	17	16.69	3.08	1.77	5.34
FACIAL SPASM	72	30	19.27	2.56	1.67	3.92	72	30	19.31	2.56	1.67	3.92
NORMAL LABOUR	44	16	13.98	2.93	1.66	5.20	33	11	11.46	3.20	1.62	6.34
ANGIOGRAM	16	3	8.39	5.69	1.66	19.53	16	3	8.40	5.70	1.66	19.55
NERVE COMPRESSION	137	66	28.93	2.21	1.65	2.97	138	66	29.64	2.23	1.67	2.99
FIBRIN D DIMER INCREASED	99	45	23.12	2.55	1.65	3.34	99	45	23.17	2.35	1.65	3.34
WHITE BLOOD CELL COUNT DECREASED	59	24	16.24	2.62	1.63	4.22	59	24	16.27	2.63	1.63	4.22
LIVE BIRTH	20	9	10.78	3.44	1.63	7.26	29	9	10.80	3.44	1.63	7.27
BLOOD LACTIC ACID INCREASED	18	4	8.56	4.80	1.63	14.19	18	4	8.57	4.81	1.63	14.20
BODY TEMPERATURE ABNORMAL	115	55	24.51	2.23	1.62	3.08	115	55	24.57	2.23	1.62	3.08
VACCINATION SITE HYPOAESTHESIA	49	19	14.34	2.75	1.62	4.67	48	19	13.63	2.70	1.59	4.59
CEREBROVASCULAR DISORDER	35	12	11.79	3.11	1.62	6.00	35	12	11.81	3.11	1.62	6.00
PERITONITIS	33	11	11.44	3.20	1.62	6.33	33	11	11.46	3.20	1.62	6.34
BASEDOW'S DISEASE	91	42	20.60	2.31	1.60	3.33	90	40	21.86	2.40	1.66	3.49
WEIGHT FLUCTUATION	24	7	9.34	3.66	1.58	8.49	24	6	10.79	4.27	1.75	10.45
SUPPRESSED LACTATION	89	42	19.30	2.26	1.57	3.26	89	42	19.34	2.26	1.57	3.27
VOCAL CORD PARALYSIS	28	9	9.97	3.32	1.57	7.03	28	9	9.99	3.32	1.57	7.04
VENTRICULAR ARRHYTHMIA	26	8	9.65	3.47	1.57	7.66	26	8	9.66	3.47	1.57	7.67
BLOOD CHOLESTEROL INCREASED	78	36	17.55	2.31	1.56	3.43	78	34	19.48	2.45	1.64	3.66
RED BLOOD CELL COUNT DECREASED	30	10	10.31	3.20	1.56	6.55	30	10	10.33	3.20	1.57	6.55
PHARYNGEAL MASS	15	3	7.46	5.34	1.54	18.43	15	3	7.47	5.34	1.55	18.44
PNEUMONIA PSEUDOMONAL	15	3	7.46	5.34	1.54	18.43	15	3	7.47	5.34	1.55	18.44
ENDOTRACHEAL INTUBATION COMPLICATION	17	4	7.67	4.53	1.53	13.48	16	4	6.80	4.27	1.43	12.78
APPENDICITIS PERFORATED	76	36	16.25	2.25	1.52	3.35	76	36	16.28	2.25	1.52	3.35
PUPILLARY REFLEX IMPAIRED	64	29	14.75	2.35	1.52	3.65	64	28	15.73	2.44	1.57	3.81
ABNORMAL UTERINE BLEEDING	57	25	13.83	2.43	1.52	3.89	56	26	12.26	2.40	1.44	3.66
OSTITIS	35	13	10.61	2.87	1.52	5.43	35	13	10.63	2.88	1.52	5.43
LACTATION DISORDER	33	12	10.24	2.93	1.52	5.68	33	12	10.26	2.94	1.52	5.69
GASTRIC DISORDER	101	51	19.16	2.11	1.51	2.96	101	51	19.20	2.11	1.51	2.96
CONVALESCENT PLASMA TRANSFUSION	44	18	11.78	2.61	1.51	4.51	44	18	11.80	2.61	1.51	4.52
RETINAL TRANSPLANT	21	6	8.20	3.73	1.51	9.25	21	6	8.22	3.74	1.51	9.26
VIRAL SIEPSIS	19	5	7.92	4.05	1.51	10.86	17	4	7.68	4.54	1.53	13.49
BLOOD BILIRUBIN INCREASED	25	8	8.84	3.35	1.50	7.39	25	8	8.85	3.34	1.51	7.40
WOUND DRAINAGE	23	7	8.51	3.51	1.50	8.17	23	7	7.72	3.36	1.43	7.86
RED BLOOD CELL SEDIMENTATION RATE	36	14	10.25	2.74	1.48	5.09	36	14	10.27	2.75	1.48	5.09
C-REACTIVE PROTEIN INCREASED	57	26	12.89	2.34	1.47	3.72	57	26	12.92	2.34	1.47	3.72
OVARIAN CYST	94	49	16.56	2.05	1.45	2.89	94	49	16.61	2.05	1.45	2.89
BLADDER DISORDER	53	24	12.09	2.36	1.45	3.82	53	25	11.22	2.26	1.41	3.64
BASAL GANGLIA INFARCTION	28	10	8.76	2.99	1.45	6.15	28	10	8.77	2.99	1.45	6.16

AUTONOMIC NERVOUS SYSTEM													
IMBALANCE	92	48	16.16	2.05	1.44	2.90	94	49	16.61	2.05	1.45	2.89	
COMA SCALE ABNORMAL	72	36	13.74	2.13	1.43	3.18	71	36	13.17	2.11	1.41	3.15	
MASTITIS	67	33	13.15	2.17	1.43	3.29	67	33	13.18	2.17	1.43	3.29	
DIANGOVER	59	28	12.40	2.25	1.43	3.53	58	28	11.79	2.21	1.41	3.47	
CERUMEN IMPACTION	20	6	7.38	3.56	1.43	8.86	20	6	7.39	3.56	1.43	8.86	
MAGNETIC RESONANCE													
IMAGING HEART	20	6	7.38	3.56	1.43	8.86	20	6	7.39	3.56	1.43	8.86	
PHARYNGEAL DISORDER	20	6	7.38	3.56	1.43	8.86	20	6	7.39	3.56	1.43	8.86	
AORTIC DISORDER	18	5	7.07	3.84	1.43	10.35	17	5	6.25	3.63	1.34	9.84	
HEMIANAESTHESIA	18	5	7.07	3.84	1.43	10.35	18	5	7.08	3.84	1.43	10.35	
NEUTROPHIL COUNT													
DECREASED	16	4	6.79	4.27	1.43	12.77	16	4	6.80	4.27	1.43	12.78	
COLOSTOMY	14	3	6.56	4.98	1.43	17.33	13	3	5.68	4.63	1.32	16.24	
SLEEP DISORDER DUE TO A													
GENERAL MEDICAL CONDITION	14	3	6.56	4.98	1.43	17.33	14	3	6.56	4.98	1.43	17.34	
VEIN DISORDER	87	46	14.78	2.02	1.41	2.88	87	46	14.82	2.02	1.41	2.89	
NASAL PRURITUS	58	28	11.76	2.21	1.41	3.47	58	30	10.17	2.06	1.33	3.21	
WRONG PATIENT	32	13	8.43	2.63	1.38	5.00	33	12	10.26	2.94	1.52	5.69	
SUBMAXILLARY GLAND													
ENLARGEMENT	25	9	7.63	2.96	1.38	6.35	25	9	7.65	2.97	1.38	6.36	
PHARYNGEAL ULCERATION	23	8	7.27	3.07	1.37	6.86	23	8	7.28	3.07	1.37	6.86	
NONINFECTIVE ENCEPHALITIS	28	11	7.65	2.72	1.35	5.46	29	11	8.39	2.82	1.41	5.64	
NAIL DISCOLOURATION	60	31	10.54	2.07	1.34	3.19	59	31	9.98	2.03	1.32	3.14	
PROTEINURIA	60	31	10.54	2.07	1.34	3.19	58	30	10.17	2.06	1.33	3.21	
ANKYLOSING SPONDYLITIS	26	10	7.27	2.77	1.34	5.75	25	10	6.57	2.67	1.28	5.56	
HORMONE LEVEL ABNORMAL	64	34	10.58	2.01	1.33	3.04	65	33	11.96	2.10	1.38	3.20	
FEBRILE NEUTROPENIA	36	16	8.24	2.40	1.33	4.33	35	16	7.60	2.34	1.29	4.22	
MEASLES	15	4	5.94	4.00	1.33	12.06	15	4	5.95	4.00	1.33	12.07	
PARENTERAL NUTRITION	15	4	5.94	4.00	1.33	12.06	14	4	5.12	3.74	1.23	11.36	
THYROIDITIS	50	25	9.33	2.13	1.32	3.45	50	25	9.35	2.14	1.32	3.45	
AZOTAEMIA	39	18	8.38	2.31	1.32	4.04	39	18	8.40	2.31	1.32	4.04	
STILLBIRTH	39	18	8.38	2.31	1.32	4.04	39	18	8.40	2.31	1.32	4.04	
RED BLOOD CELL													
TRANSFUSION	29	12	7.33	2.58	1.32	5.05	26	10	7.28	2.78	1.34	5.76	
DECREASED NASOLABIAL FOLD	24	9	6.89	2.85	1.32	6.12	24	9	6.90	2.85	1.32	6.13	
GESTATIONAL DIABETES	22	8	6.51	2.93	1.31	6.59	22	8	6.53	2.94	1.31	6.60	
PHARYNGITIS STREPTOCOCCAL	57	30	9.56	2.03	1.30	3.15	57	30	9.58	2.03	1.30	3.16	
INTRACRANIAL PRESSURE													
INCREASED	40	19	8.15	2.25	1.30	3.88	41	18	9.72	2.43	1.40	4.23	
ACUTE CARDIAC EVENT	27	11	6.94	2.62	1.30	5.28	27	11	6.96	2.62	1.30	5.28	
TIC	49	25	8.73	2.09	1.29	3.39	49	25	8.75	2.09	1.29	3.39	
VISUAL ACUTY REDUCED	50	26	8.54	2.05	1.28	3.30	50	24	10.18	2.22	1.37	3.62	
BLOOD THYROID STIMULATING													
HORMONE INCREASED	30	13	7.04	2.46	1.28	4.72	30	13	7.06	2.46	1.29	4.72	
CARDIAC VALVE DISEASE	30	13	7.04	2.46	1.28	4.72	30	13	7.06	2.46	1.29	4.72	
ENDOMETRIAL THICKENING	25	10	6.55	2.67	1.28	5.55	25	10	6.57	2.67	1.28	5.56	
EYE OEDEMA	25	10	6.55	2.67	1.28	5.55	25	10	6.57	2.67	1.28	5.56	
PETIT MAL EPILEPSY	28	12	6.65	2.49	1.27	4.90	28	12	6.66	2.49	1.27	4.90	
LABILE BLOOD PRESSURE	18	6	5.79	3.20	1.27	8.06	18	6	5.80	3.20	1.27	8.07	
PLATELET COUNT INCREASED	31	14	6.78	2.36	1.26	4.44	31	14	6.80	2.36	1.26	4.44	
DYSAESTHESIA	37	18	7.12	2.19	1.25	3.85	36	18	6.53	2.14	1.21	3.76	
OCULAR ICTERUS	37	18	7.12	2.19	1.25	3.85	37	18	7.14	2.20	1.25	3.86	
ELECTROCARDIOGRAM ST													
SEGMENT ABNORMAL	34	16	6.94	2.27	1.25	4.11	32	15	6.56	2.28	1.23	4.21	
NIH STROKE SCALE	34	16	6.94	2.27	1.25	4.11	34	16	6.96	2.27	1.25	4.11	

WOUND INFECTION	26	11	6.25	2.52	1.25	5.10	26	11	6.26	2.52	1.25	5.11
FACTOR V LEIDEN MUTATION	16	5	5.44	3.41	1.25	9.32	16	5	5.45	3.42	1.25	9.33
DEPERSONALISATION/DEREALISATION DISORDER	29	13	6.38	2.38	1.24	4.58	30	13	7.06	2.46	1.29	4.72
UTERINE PAIN	38	19	6.92	2.13	1.23	3.70	38	19	6.94	2.14	1.23	3.70
ANTIALLERGIC THERAPY	32	15	6.54	2.28	1.23	4.20	32	15	6.56	2.28	1.23	4.21
HAEMOTHORAX	14	4	5.11	3.73	1.23	11.35	14	4	5.12	3.74	1.23	11.36
CORONARY ANGIOPLASTY	27	12	5.98	2.40	1.22	4.74	27	12	5.99	2.40	1.22	4.74
BLOOD SODIUM DECREASED	24	10	5.86	2.56	1.22	5.35	24	10	5.87	2.56	1.23	5.36
ESCHERICHIA URINARY TRACT INFECTION	19	7	5.40	2.90	1.22	6.89	19	7	5.41	2.90	1.22	6.90
POSTPARTUM HAEMORRHAGE	19	7	5.40	2.90	1.22	6.89	19	7	5.41	2.90	1.22	6.90
CEREBRAL ARTERY DISSECTION	19	7	5.40	2.90	1.22	6.89	18	7	4.69	2.75	1.15	6.57
WALKING DISABILITY	33	16	6.32	2.20	1.21	4.00	32	16	5.73	2.14	1.17	3.89
ALANINE AMINOTRANSFERASE INCREASED	40	21	6.55	2.03	1.20	3.45	40	21	6.57	2.03	1.20	3.45
SICK RELATIVE	37	19	6.33	2.08	1.20	3.61	36	19	5.77	2.02	1.16	3.53
RENAL MASS	22	9	5.46	2.61	1.20	5.66	21	9	4.79	2.49	1.14	5.44
FOETAL HYPOKINESIA	34	17	6.12	2.13	1.19	3.82	33	17	5.55	2.07	1.15	3.72
INTESTINAL PERFORATION	25	11	5.58	2.43	1.19	4.93	24	11	4.95	2.33	1.14	4.76
PROTEIN URINE PRESENT	17	6	5.03	3.02	1.19	7.67	17	6	5.04	3.03	1.19	7.67
PELVIC VEIN THROMBOSIS	26	12	5.34	2.31	1.17	4.58	26	12	5.35	2.31	1.17	4.59
ABDOMINAL MASS	23	10	5.18	2.45	1.17	5.16	22	9	5.47	2.61	1.20	5.67
INCORRECT PRODUCT ADMINISTRATION DURATION	23	10	5.18	2.45	1.17	5.16	23	10	5.19	2.46	1.17	5.16
PHONOPHORIA	23	10	5.18	2.45	1.17	5.16	23	10	5.19	2.46	1.17	5.16
CORPULMONALE	20	8	5.07	2.67	1.17	6.06	19	7	5.41	2.90	1.22	6.90
MENINGITIS VIRAL	20	8	5.07	2.67	1.17	6.06	19	8	4.39	2.54	1.11	5.79
COMPLICATED APPENDICITIS	15	5	4.66	3.20	1.16	8.81	15	5	4.67	3.20	1.16	8.81
COMPUTERISED TOMOGRAPHY THORAX	15	5	4.66	3.20	1.16	8.81	15	5	4.67	3.20	1.16	8.81
PNEUMOMEDIASTINUM	33	17	5.53	2.07	1.15	3.72	33	17	5.55	2.07	1.15	3.72
EPICONDYLITIS	30	15	5.32	2.13	1.15	3.97	30	14	6.15	2.29	1.21	4.32
HEPATIC MASS	30	15	5.32	2.13	1.15	3.97	30	15	5.33	2.14	1.15	3.97
SPINAL DISORDER	30	15	5.32	2.13	1.15	3.97	30	15	5.33	2.14	1.15	3.97
PNEUMOPERITONEUM	18	7	4.68	2.74	1.15	6.57	18	7	4.69	2.75	1.15	6.57
CLONUS	27	13	5.12	2.22	1.14	4.29	27	13	5.13	2.22	1.14	4.30
HYPOSMOLAR STATE	27	13	5.12	2.22	1.14	4.29	27	13	5.13	2.22	1.14	4.30
PATIENT UNCOOPERATIVE	27	13	5.12	2.22	1.14	4.29	26	13	4.53	2.14	1.10	4.16
HEARING AID USER	31	16	5.13	2.07	1.13	3.78	31	16	5.15	2.07	1.13	3.78
PENILE PAIN	13	4	4.31	3.47	1.13	10.64	13	4	4.31	3.47	1.13	10.64
POSTPARTUM STATE	13	4	4.31	3.47	1.13	10.64	13	4	4.31	3.47	1.13	10.64
THERAPEUTIC PRODUCT EFFECT DECREASED	13	4	4.31	3.47	1.13	10.64	13	4	4.31	3.47	1.13	10.64
CONVERSION DISORDER	32	17	4.96	2.01	1.12	3.62	32	16	5.73	2.14	1.17	3.89
BRONCHIAL SECRETION RETENTION	29	15	4.74	2.06	1.11	3.85	29	15	4.75	2.06	1.11	3.85
LABORATORY TEST ABNORMAL	29	15	4.74	2.06	1.11	3.85	29	15	4.75	2.06	1.11	3.85
MICROCYTIC ANAEMIA	29	15	4.74	2.06	1.11	3.85	29	15	4.75	2.06	1.11	3.85
THYROID PAIN	22	10	4.53	2.35	1.11	4.96	22	10	4.54	2.35	1.11	4.96
MUSCLE RUPTURE	19	8	4.39	2.53	1.11	5.79	19	8	4.39	2.54	1.11	5.79
NECROSIS	19	8	4.39	2.53	1.11	5.79	19	8	4.39	2.54	1.11	5.79
ORTHOSTATIC HYPERTENSION	19	8	4.39	2.53	1.11	5.79	19	8	4.39	2.54	1.11	5.79

BLOOD POTASSIUM INCREASED	16	6	4.29	2.85	1.11	7.27	16	6	4.30	2.85	1.11	7.28
CIRRHOSIS ALCOHOLIC	16	6	4.29	2.85	1.11	7.27	16	6	4.30	2.85	1.11	7.28
COMPLICATION OF PREGNANCY	16	6	4.29	2.85	1.11	7.27	16	6	4.30	2.85	1.11	7.28
ALCOHOL WITHDRAWAL SYNDROME	23	11	4.31	2.23	1.09	4.58	23	11	4.32	2.23	1.09	4.58
HIDRADENITIS	23	11	4.31	2.23	1.09	4.58	23	11	4.32	2.23	1.09	4.58
MITRAL VALVE CALCIFICATION	23	11	4.31	2.23	1.09	4.58	23	10	5.19	2.46	1.17	5.16
NIH STROKE SCALE SCORE INCREASED	27	14	4.34	2.06	1.08	3.92	27	13	5.13	2.22	1.14	4.20
ILLUSION	20	9	4.13	2.37	1.08	5.21	20	9	4.14	2.37	1.08	5.21
SOCIAL AVOIDANT BEHAVIOUR	20	9	4.13	2.37	1.08	5.21	20	8	5.08	2.67	1.18	6.06
BLOOD CREATINE PHOSPHOKINASE INCREASED	24	12	4.12	2.13	1.07	4.27	24	11	4.95	2.33	1.14	4.76
CEREBRAL ARTERY STENOSIS	24	12	4.12	2.13	1.07	4.27	24	12	4.13	2.14	1.07	4.27
CERVICAL RADICULOPATHY	24	12	4.12	2.13	1.07	4.27	24	11	4.95	2.33	1.14	4.76
MENISCUS INJURY	24	12	4.12	2.13	1.07	4.27	24	12	4.13	2.14	1.07	4.27
PROSTATE CANCER	31	16	5.13	2.07	1.13	3.78	29	16	4.04	1.94	1.05	3.56
BODY HEIGHT DECREASED	55	2	50.93	29.34	7.16	120.29	55	2	50.98	29.37	7.16	120.40
PRODUCT LOT NUMBER ISSUE	25	1	21.89	26.68	3.61	196.86	25	1	21.91	26.70	3.62	197.03
SALIVARY GLAND PAIN	18	2	12.26	9.60	2.23	41.39	18	2	12.27	9.61	2.23	41.42
PNEUMOTHORAX SPONTANEOUS	17	2	11.26	9.07	2.10	39.25	17	2	11.27	9.08	2.10	39.29
ELDERLY	13	2	7.34	6.94	1.57	30.73	13	2	7.35	6.94	1.57	30.76
LYMPHOCYTE COUNT DECREASED	13	2	7.34	6.94	1.57	30.73	13	2	7.35	6.94	1.57	30.76
OCULAR VASCULAR DISORDER	13	2	7.34	6.94	1.57	30.73	13	2	7.35	6.94	1.57	30.76
CEREBROSPINAL FLUID LEAKAGE	11	1	7.35	11.74	1.52	90.91	11	1	7.36	11.75	1.52	90.99
CYST RUPTURE	12	2	6.39	6.40	1.43	28.60	12	2	6.40	6.41	1.43	28.63
HYPOAESTHESIA TEETH	12	2	6.39	6.40	1.43	28.60	12	2	6.40	6.41	1.43	28.63
INTERVERTEBRAL DISCITIS	12	2	6.39	6.40	1.43	28.60	12	2	6.40	6.41	1.43	28.63
MENORRHAGIA	12	2	6.39	6.40	1.43	28.60	12	2	6.40	6.41	1.43	28.63
ALOPECIA UNIVERSALIS	10	1	6.36	10.67	1.37	83.35	10	1	6.36	10.68	1.37	83.42
ENTEROBACTER INFECTION	10	1	6.36	10.67	1.37	83.35	10	1	6.36	10.68	1.37	83.42
THERAPEUTIC RESPONSE SHORTENED	10	1	6.36	10.67	1.37	83.35	10	1	6.36	10.68	1.37	83.42
ACUTE STRESS DISORDER	11	2	5.46	5.87	1.30	26.48	11	2	5.47	5.87	1.30	26.50
BLOOD MAGNESIUM DECREASED	11	2	5.46	5.87	1.30	26.48	11	2	5.47	5.87	1.30	26.50
MUTISM	11	2	5.46	5.87	1.30	26.48	11	2	5.47	5.87	1.30	26.50
CHRONIC PIGMENTED PURPURA	9	1	5.37	9.60	1.22	75.80	9	1	5.38	9.61	1.22	75.86
GASTRITIS EROSIVE	9	1	5.37	9.60	1.22	75.80	9	1	5.38	9.61	1.22	75.86
OBSTRUCTIVE SLEEP APNOEA SYNDROME	9	1	5.37	9.60	1.22	75.80	9	1	5.38	9.61	1.22	75.86
ECHOCARDIOGRAM ABNORMAL	10	2	4.53	5.34	1.17	24.35	10	2	4.56	5.34	1.17	24.37
LOW DENSITY LIPOPROTEIN INCREASED	10	2	4.53	5.34	1.17	24.35	10	2	4.56	5.34	1.17	24.37
PERICARDIAL DISEASE	10	2	4.53	5.34	1.17	24.35	10	2	4.56	5.34	1.17	24.37
ANGLE CLOSURE GLAUCOMA	8	1	4.40	8.54	1.07	68.25	8	1	4.41	8.54	1.07	68.31
NEOPLASM PROGRESSION	8	1	4.40	8.54	1.07	68.25	8	1	4.41	8.54	1.07	68.31
POIKILOCYTOSIS	8	1	4.40	8.54	1.07	68.25	8	1	4.41	8.54	1.07	68.31
RED CELL DISTRIBUTION WIDTH INCREASED	8	1	4.40	8.54	1.07	68.25	8	1	4.41	8.54	1.07	68.31
SALIVARY GLAND MASS	8	1	4.40	8.54	1.07	68.25	8	1	4.41	8.54	1.07	68.31
SCIATIC NERVE INJURY	8	1	4.40	8.54	1.07	68.25	8	1	4.41	8.54	1.07	68.31

VIRAL PHARYNGITIS	8	1	4.40	8.54	1.07	68.25	8	1	4.41	8.54	1.07	68.31
POSTURAL ORTHOSTATIC TACHYCARDIA SYNDROME	140	75	23.46	1.99	1.50	2.64	142	75	24.68	2.02	1.53	2.67
ALOPECIA AREATA	66	37	9.55	1.90	1.27	2.85	66	35	11.00	2.01	1.34	3.03
LANGUAGE DISORDER	23	11	3.72	2.13	1.03	4.40	23	11	4.32	2.23	1.09	4.58
CORRECTIVE LENS USER	20	10	3.32	2.13	1.00	4.56	20	9	4.14	2.37	1.08	5.21

PREFERRED Medical Dictionary for Regulatory Activities (MedDRA) Terms (VAERS - Box 7, VAERS 2.0 Box 18)

For Current Week and Past Week Comparison

Following ALL 12/14/2020-04/15/2022 COVID19 Pfizer Ages 18+ Vaccines

Compared to ALL 12/14/2020-04/15/2022 COVID19 Moderna Ages 18+ Vaccines

SERIOUS AGES 18+ YEARS, Initial domestic reports only, VAERS reports as of 04/15/2022

Vaccination, Received, and Completed Date: 12/14 - 04/15 (Current Week) and 12/14 - 04/08 (Past Week)

N>=3 (Current Week), PRR=2.00 (Ratio of Proportions), Chi-Square=4.00

MedDRA PTs sorting based on lower confidence limit and PFIZER adverse event count from 12/14/2020-04/15/2022

SERIOUS AGES 18+ YEARS excludes missing ages

MedDRA Codes ALL Reports (SERIOUS 18+)	12/14/2020- 04/15/2022 PFIZER N=36782	12/14/2020- 04/15/2022 MODERNA N=30088	12/14-04/15 Chi-Square	12/14-04/15 PRR	12/14-04/15 LCL	12/14-04/15 UCL	12/14/2020- 04/08/2022 PFIZER N=36603	12/14/2020- 04/08/2022 MODERNA N=29929	12/14-04/08 Chi-Square	12/14-04/08 PRR	12/14-04/08 LCL	12/14-04/08 UCL
AMUCINATION	132	8	85.88	13.50	6.61	27.55	130	8	84.23	13.29	6.51	27.13
APPARENT LIFE THREATENING EVENT	61	7	31.73	7.13	3.26	15.58	61	7	31.71	7.13	3.26	15.57
VACCINATION FAILURE	65	9	30.95	5.91	2.94	11.86	65	6	36.87	8.86	3.84	20.44
DRUG INEFFECTIVE	108	25	35.90	3.53	2.29	5.46	108	25	35.88	3.53	2.29	5.46
WHITE BLOOD CELL COUNT INCREASED	46	8	18.69	4.70	2.22	9.96	46	8	18.68	4.70	2.22	9.96
DISEASE RECURRENCE	33	5	14.31	5.40	2.11	13.83	33	5	14.30	5.40	2.11	13.82
VIBRATORY SENSE INCREASED	24	3	11.20	6.54	1.97	21.73	24	3	11.19	6.54	1.97	21.72
OFF LABEL USE	74	21	19.22	2.88	1.78	4.68	74	21	19.21	2.88	1.78	4.68
EATING DISORDER	44	12	11.64	3.00	1.58	5.68	44	12	11.63	3.00	1.58	5.68
OSTEOPEINIA	27	7	7.23	3.16	1.37	7.24	27	7	7.22	3.15	1.37	7.24
NEAR DEATH EXPERIENCE	47	16	9.01	2.40	1.36	4.24	47	16	9.00	2.40	1.36	4.23
VERTEBRAL ARTERY DISSECTION	17	3	6.11	4.64	1.36	15.82	16	3	5.42	4.36	1.27	14.96
PERITONITIS	31	9	7.30	2.82	1.34	5.92	31	9	7.29	2.82	1.34	5.91
BLOOD CHOLESTEROL INCREASED	24	6	6.60	3.27	1.34	8.00	24	6	6.59	3.27	1.34	8.00
MOANING	64	26	8.81	2.01	1.28	3.18	64	26	8.79	2.01	1.28	3.17
NORMAL LABOUR	44	16	7.43	2.25	1.27	3.99	33	11	6.32	2.45	1.24	4.85
PHOTOPSIA	47	19	6.37	2.02	1.19	3.45	47	19	6.36	2.02	1.19	3.45
PNEUMONIA PSEUDOMONAL	15	3	4.75	4.09	1.18	14.13	15	3	4.75	4.09	1.18	14.12
VEIN DISORDER	15	3	4.75	4.09	1.18	14.13	15	3	4.75	4.09	1.18	14.12
ENDOTRACHEAL INTUBATION COMPLICATION	17	4	4.71	3.48	1.17	10.33	16	4	4.09	3.27	1.09	9.78
RENAL TRANSPLANT	21	6	4.78	2.86	1.16	7.09	21	6	4.77	2.86	1.16	7.09
VIRAL SEPSIS	19	5	4.73	3.11	1.16	8.32	17	4	4.71	3.48	1.17	10.33
BASAL GANGLIA INFARCTION	27	9	5.04	2.45	1.15	5.22	27	9	5.03	2.45	1.15	5.22
PHOTOSENSITIVITY REACTION	35	8	4.94	2.56	1.15	5.67	35	7	6.01	2.92	1.26	6.75
BLOOD DISORDER	24	8	4.30	2.45	1.10	5.46	24	8	4.39	2.45	1.10	5.46
SALIVARY HYPERSECRETION	22	7	4.29	2.57	1.10	6.02	22	7	4.29	2.57	1.10	6.01
DECREASED NASOLABIAL FOLD	20	6	4.20	2.73	1.10	6.79	20	6	4.20	2.73	1.09	6.79
FACIAL SPASM	14	3	4.09	3.82	1.10	13.28	14	3	4.09	3.82	1.10	13.28
MUSCLE FATIGUE	33	13	4.55	3.94	1.09	3.94	33	12	5.39	2.25	1.16	4.35
BREAST CANCER FEMALE	31	12	4.41	2.11	1.09	4.11	30	11	4.75	2.23	1.12	4.45
MAST CELL ACTIVATION SYNDROME	18	5	4.13	2.94	1.09	7.91	19	5	4.72	3.11	1.16	8.32
VOCAL CORD PARALYSIS	16	4	4.09	3.27	1.09	9.79	16	4	4.09	3.27	1.09	9.78
COLOSTOMY	14	3	4.09	3.82	1.10	13.28	13	3	3.45	3.54	1.01	12.43
PRODUCT USE ISSUE	28	2	16.30	11.45	2.73	48.07	28	2	16.29	11.45	2.73	48.05
LIVE BIRTH	21	2	10.82	8.59	2.01	36.63	21	2	10.82	8.59	2.01	36.61
MENISCUS INJURY	14	1	7.42	11.45	1.51	87.08	14	1	7.42	11.45	1.51	87.05

PNELMOTIIRAX	16	2	7.04	6.54	1.50	28.46	16	2	7.03	6.54	1.50	28.45
SPONTANEOUS												
ELDERLY	13	1	6.65	10.63	1.39	81.28	13	1	6.65	10.63	1.39	81.25
CLUSTER HEADACHE	13	2	4.86	5.32	1.20	23.56	12	2	4.16	4.91	1.10	21.92
BODY TEMPERATURE												
FLUCTUATION	12	2	4.17	4.91	1.10	21.93	12	2	4.16	4.91	1.10	21.92
ENTEROBACTER INFECTION	10	1	4.37	8.18	1.05	63.90	10	1	4.37	8.18	1.05	63.87
AUTONOMIC NERVOUS SYSTEM												
IMBALANCE	41	17	5.15	1.97	1.12	3.47	42	17	5.60	2.02	1.15	3.55

PREFERRED Medical Dictionary for Regulatory Activities (MedDRA) Terms (VAERS-1 Box 7, VAERS 2.0 Box 18)

For Current Week and Past Week Comparison

Following **ALL 12/14/2020-04/15/2022 COVID19 Pfizer Ages 18+ Vaccines**

Compared to **ALL 12/14/2020-04/15/2022 COVID19 Moderna Ages 18+ Vaccines**

NON-SERIOUS AGES 18+ YEARS, Initial domestic reports only, VAERS reports as of 04/15/2022

Vaccination, Received, and Completed Date: 12/14 - 04/15 (Current Week) and 12/14 - 04/08 (Past Week)

N₀≥3 (Current Week), PRR₀≥2.00 (Ratio of Proportions), Chi-Square₀≥4.00

MedDRA PTs sorting based on lower confidence limit and PFIZER adverse event count from 12/14/2020-04/15/2022

NON-SERIOUS AGES 18+ YEARS excludes missing ages

MedDRA Codes ALL Reports (NON-SERIOUS 18+)	12/14/2020- 04/15/2022 PFIZER N=266340	12/14/2020- 04/15/2022 MODERNA N=293345	12/14-04/15 Chi-Square	12/14-04/15 PRR	12/14-04/15 LCL	12/14-04/15 UCL	12/14/2020- 04/08/2022 PFIZER N=265798	12/14/2020- 04/08/2022 MODERNA N=293015	12/14-04/08 Chi-Square	12/14-04/08 PRR	12/14-04/08 LCL	12/14-04/08 UCL
PRODUCT PREPARATION ERROR	556	15	566.02	40.82	24.45	68.18	555	15	565.46	40.79	24.42	68.12
VACCINATION FAILURE	912	45	872.97	22.32	16.55	30.11	908	45	869.46	22.24	16.49	30.00
DISEASE RECURRENT	183	6	181.80	33.59	14.90	75.75	182	6	180.88	33.44	14.83	75.41
PRODUCT PREPARATION ISSUE	2102	166	1854.72	13.95	11.91	16.33	2104	167	1856.32	13.89	11.87	16.26
PRODUCT USE ISSUE	404	25	371.69	17.80	11.88	26.66	404	25	372.07	17.81	11.90	26.68
IMMUNISATION	2385	207	2058.87	12.69	11.01	14.62	2385	207	2061.08	12.70	11.02	14.64
IMMUNODEFICIENCY	410	61	292.73	7.40	5.66	9.69	409	60	294.17	7.51	5.73	9.85
CIRCUMSTANCE OR INFORMATION CAPABLE OF LEADING TO MEDICATION ERROR	118	17	84.25	7.64	4.60	12.71	118	17	84.36	7.65	4.60	12.72
OFF LABEL USE	899	190	533.43	5.21	4.46	6.09	898	190	533.17	5.21	4.46	6.09
DRUG INEFFECTIVE	915	242	459.87	4.16	3.61	4.80	913	241	460.30	4.18	3.62	4.81
INCORRECT PRODUCT FORMULATION ADMINISTERED	546	162	246.68	3.71	3.12	4.42	546	162	247.07	3.72	3.12	4.43
MIDDLE INSOMNIA	72	15	41.76	5.29	3.03	9.22	72	15	41.81	5.29	3.03	9.23
OVERDOSE	151	46	65.57	3.62	2.60	5.03	151	46	65.68	3.62	2.60	5.03
INTERCHANGE OF VACCINE PRODUCTS	5728	2579	1542.51	2.45	2.34	2.56	5716	2576	1540.19	2.45	2.34	2.56
CROHN'S DISEASE	92	31	35.43	3.27	2.18	4.91	92	31	35.50	3.27	2.18	4.91
DRUG HYPERSENSITIVITY	149	57	49.59	2.88	2.12	3.91	148	57	48.90	2.86	2.11	3.89
EAR DISORDER	94	34	33.27	3.05	2.06	4.51	94	34	33.33	3.05	2.06	4.51
NEAR DEATH EXPERIENCE	59	19	23.50	3.42	2.04	5.74	59	19	23.54	3.42	2.04	5.74
EXPOSURE TO SARS-COV-2	792	383	184.60	2.28	2.02	2.57	785	379	183.95	2.28	2.02	2.58
SKIN DISORDER	332	100	65.29	2.56	2.02	3.23	331	100	64.70	2.55	2.01	3.22
POLYMERORRHOEA	447	208	111.36	2.37	2.01	2.79	446	208	110.92	2.36	2.01	2.79
UTERINE HAEMORRHAGE	56	18	22.30	3.43	2.01	5.83	56	18	22.34	3.43	2.02	5.83
ASYMPTOMATIC COVID-19	332	151	85.85	2.42	2.00	2.94	325	151	81.12	2.37	1.96	2.88
UPPER RESPIRATORY TRACT CONGESTION	93	35	31.26	2.93	1.98	4.32	93	34	32.52	3.02	2.04	4.47
MENSTRUAL DISORDER	1550	808	311.89	2.11	1.94	2.30	1553	807	315.43	2.12	1.95	2.31
HYPOMENORRHOEA	114	46	34.99	2.73	1.94	3.84	114	46	35.06	2.73	1.94	3.85
INTERMENSTRUAL BLEEDING	852	435	178.43	2.16	1.92	2.42	848	433	177.99	2.16	1.92	2.42
STRIDOR	75	28	25.29	2.95	1.91	4.55	75	28	25.33	2.95	1.91	4.56
MENSTRUATION IRREGULAR	2010	1094	368.14	2.02	1.88	2.18	2006	1093	367.49	2.02	1.88	2.18
ANTINUCLEAR ANTIBODY POSITIVE	20	4	10.90	5.51	1.88	16.11	20	4	10.92	5.51	1.88	16.13
NERVE COMPRESSION	122	52	34.52	2.58	1.87	3.57	123	52	35.33	2.61	1.89	3.61
FIBRIN D DIMER INCREASED	52	18	18.95	3.18	1.86	5.44	52	18	18.99	3.18	1.86	5.44
DYSMENORRHOEA	1134	611	211.74	2.04	1.85	2.26	1130	612	209.08	2.04	1.85	2.25
ELECTROCARDIOGRAM ABNORMAL	40	13	15.42	3.39	1.81	6.34	40	13	15.45	3.39	1.81	6.34
SUSPECTED COVID-19	254	127	54.88	2.20	1.78	2.73	254	127	55.01	2.20	1.78	2.73

REFUSAL OF TREATMENT BY PATIENT	75	31	21.89	2.66	1.75	4.05	76	31	22.69	2.70	1.78	4.10
RED BLOOD CELL COUNT DECREASED	23	6	10.46	4.22	1.72	10.37	23	6	10.48	4.23	1.72	10.38
ANTIALLERGIC THERAPY	16	3	8.80	5.87	1.71	20.16	16	3	8.81	5.88	1.71	20.18
BLOOD THYROID STIMULATING HORMONE INCREASED	27	8	11.10	3.72	1.69	8.18	27	8	11.12	3.72	1.69	8.19
RED BLOOD CELL SEDIMENTATION RATE INCREASED	27	8	11.10	3.72	1.69	8.18	27	8	11.12	3.72	1.69	8.19
SUPPRESSED LACTATION	89	41	21.89	2.39	1.65	3.46	89	41	21.94	2.39	1.65	3.46
WHITE BLOOD CELL COUNT INCREASED	67	29	18.10	2.54	1.65	3.93	66	29	17.42	2.51	1.62	3.88
GASTRIC DISORDER	87	41	20.51	2.34	1.61	3.39	86	41	19.88	2.31	1.59	3.35
BODY TEMPERATURE ABNORMAL	105	52	22.67	2.22	1.60	3.10	105	52	22.72	2.23	1.60	3.10
MEASLES	15	3	7.84	5.51	1.59	19.02	15	3	7.86	5.51	1.60	19.04
PHARYNGEAL MASS	15	3	7.84	5.51	1.59	19.02	15	3	7.86	5.51	1.60	19.04
WEIGHT FLUCTUATION	15	3	7.84	5.51	1.59	19.02	15	3	7.86	5.51	1.60	19.04
JAW DISORDER	68	31	16.84	2.42	1.58	3.69	68	31	16.88	2.42	1.58	3.70
LACTATION DISORDER	33	12	10.95	3.03	1.56	5.86	33	12	10.97	3.03	1.57	5.87
MOOD ALTERED	104	53	21.17	2.16	1.55	3.01	104	53	21.22	2.16	1.55	3.01
VAGINAL DISCHARGE	84	41	18.50	2.26	1.55	3.28	83	41	17.89	2.23	1.54	3.24
EYE OEDEMA	23	7	9.04	3.62	1.55	8.43	23	7	9.05	3.62	1.55	8.44
VACCINATION SITE HYPOAESTHESIA	43	18	11.93	2.63	1.52	4.56	42	18	11.23	2.57	1.48	4.47
WHITE BLOOD CELL COUNT DECREASED	48	21	12.50	2.52	1.51	4.20	49	21	13.24	2.57	1.54	4.29
BONE DISORDER	32	12	10.16	2.94	1.51	5.70	32	12	10.18	2.94	1.51	5.71
FACIAL SPASM	58	27	13.72	2.37	1.50	3.74	58	27	13.75	2.37	1.50	3.74
UTERINE SPASM	79	40	16.12	2.18	1.49	3.18	79	40	16.16	2.18	1.49	3.18
C-REACTIVE PROTEIN INCREASED	37	15	10.65	2.72	1.49	4.95	37	15	10.68	2.72	1.49	4.95
HAEMOGLOBIN DECREASED	37	15	10.65	2.72	1.49	4.95	37	16	9.64	2.55	1.42	4.58
PSORIATIC ARTHROPATHY	54	25	12.84	2.38	1.48	3.82	53	26	11.31	2.25	1.41	3.59
ANKYLOSING SPONDYLITIS	24	8	8.57	3.30	1.48	7.35	23	8	7.78	3.17	1.42	7.09
WALKING DISABILITY	22	7	8.20	3.46	1.48	8.10	22	7	8.21	3.46	1.48	8.11
BLOOD BILIRUBIN INCREASED	14	3	6.90	5.14	1.48	17.88	14	3	6.91	5.14	1.48	17.90
BASEDOW'S DISEASE	57	27	13.04	2.33	1.47	3.68	57	26	14.00	2.42	1.52	3.84
ROAD TRAFFIC ACCIDENT	57	27	13.04	2.33	1.47	3.68	56	27	12.40	2.29	1.44	3.62
HANGOVER	58	28	12.81	2.28	1.45	3.58	57	28	12.18	2.24	1.43	3.53
NASAL PRURITUS	57	28	12.15	2.24	1.43	3.52	57	30	10.54	2.09	1.35	3.26
SPECTUM DISCOLOURED	68	35	13.30	2.14	1.42	3.22	69	34	14.82	2.24	1.48	3.37
MASTITIS	63	32	12.62	2.17	1.42	3.32	63	32	12.65	2.17	1.42	3.32
WRONG PATIENT	33	13	9.06	2.71	1.42	5.17	33	12	10.97	3.03	1.57	5.87
OVARIAN CYST	69	36	13.12	2.11	1.41	3.16	69	36	13.15	2.11	1.41	3.16
FRUSTRATION TOLERANCE DECREASED	67	35	12.68	2.11	1.40	3.17	66	35	12.10	2.08	1.38	3.13
APRAXIA	19	6	6.99	3.49	1.39	8.73	19	6	7.01	3.49	1.39	8.74
PLATELET COUNT INCREASED	26	10	7.80	2.86	1.38	5.94	26	10	7.82	2.87	1.38	5.94
MAST CELL ACTIVATION SYNDROME	31	13	8.33	2.63	1.37	5.02	30	12	8.66	2.76	1.41	5.38
PETIT MAL EPILEPSY	24	9	7.38	2.94	1.37	6.32	24	9	7.40	2.94	1.37	6.32
PHARYNGITIS STREPTOCOCCAL	50	25	10.20	2.20	1.36	3.56	50	25	10.22	2.20	1.36	3.56
SLEEP DISORDER DUE TO A GENERAL MEDICAL CONDITION	13	3	5.98	4.77	1.36	16.75	13	3	5.99	4.78	1.36	16.76
INCREASED APPETITE	54	28	10.25	2.12	1.35	3.35	54	28	10.28	2.13	1.35	3.36
EPICONDYLITIS	27	11	7.47	2.70	1.34	5.45	27	10	8.59	2.98	1.44	6.15

HORMONE LEVEL ABNORMAL	55	29	10.07	2.09	1.33	3.28	55	28	10.90	2.17	1.37	3.41
NAIL DISCOLOURATION	53	28	9.64	2.08	1.32	3.30	53	28	9.67	2.09	1.32	3.30
ABNORMAL UTERINE BLEEDING	39	19	8.21	2.26	1.31	3.91	38	19	7.59	2.20	1.27	3.82
HYPORESPOSIVE TO STIMULI	23	9	6.63	2.81	1.30	6.08	23	9	6.64	2.82	1.30	6.09
SUBMAXILLARY GLAND ENLARGEMENT	23	9	6.63	2.81	1.30	6.08	23	9	6.64	2.82	1.30	6.09
RETINAL VEIN OCCLUSION	34	16	7.56	2.34	1.29	4.24	34	16	7.57	2.34	1.29	4.24
CLAUSTROPHOBIA	16	5	5.79	3.52	1.29	9.62	16	5	5.80	3.53	1.29	9.63
DEMYELINATION	16	5	5.79	3.52	1.29	9.62	17	6	5.39	3.12	1.23	7.92
PHARYNGEAL DISORDER	16	5	5.79	3.52	1.29	9.62	16	5	5.81	3.53	1.29	9.63
ATELECTASIS	50	27	8.61	2.04	1.28	3.26	50	26	9.40	2.12	1.33	3.41
TITIDITIS	44	23	8.08	2.11	1.27	3.49	44	23	8.10	2.11	1.27	3.49
CEREBRAL INFARCTION	12	3	5.09	4.41	1.24	15.61	12	3	5.09	4.41	1.24	15.63
SICK RELATIVE	12	3	5.09	4.41	1.24	15.61	12	3	5.09	4.41	1.24	15.63
BREAST ENLARGEMENT	42	23	6.89	2.01	1.21	3.34	42	23	6.91	2.01	1.21	3.35
MENTAL FATIGUE	42	23	6.89	2.01	1.21	3.34	42	23	6.91	2.01	1.21	3.35
UTERINE PAIN	35	18	6.51	2.14	1.21	3.78	35	18	6.53	2.14	1.21	3.78
INCORRECT PRODUCT ADMINISTRATION DURATION	23	10	5.61	2.53	1.21	5.32	23	10	5.62	2.54	1.21	5.33
PHARYNGEAL ULCERATION	20	8	5.46	2.75	1.21	6.25	20	8	5.47	2.76	1.21	6.26
POST-TRAUMATIC STRESS DISORDER	20	8	5.46	2.75	1.21	6.25	20	8	5.47	2.76	1.21	6.26
VIBRATORY SENSE INCREASED	39	21	6.61	2.05	1.20	3.48	40	21	7.23	2.10	1.24	3.56
POLYURIA	36	19	6.34	2.09	1.20	3.64	36	19	6.36	2.09	1.20	3.64
GINGIVAL DISORDIR	15	5	4.98	3.30	1.20	9.09	15	5	4.99	3.31	1.20	9.10
BLADDER DISORDER	33	17	6.08	2.14	1.19	3.84	33	18	5.34	2.02	1.14	3.59
NEOPLASM	33	17	6.08	2.14	1.19	3.84	33	17	6.09	2.14	1.19	3.84
TIC	33	17	6.08	2.14	1.19	3.84	33	17	6.09	2.14	1.19	3.84
TOOTH DISORDER	33	17	6.08	2.14	1.19	3.84	33	17	6.09	2.14	1.19	3.84
LABORATORY TEST ABNORMAL	18	7	5.04	2.83	1.18	6.78	18	7	5.05	2.83	1.18	6.79
POLYARTHRITIS	31	16	5.64	2.13	1.17	3.90	31	17	4.91	2.01	1.11	3.63
BLOOD POTASSIUM INCREASED	13	4	4.59	3.58	1.17	10.98	13	4	4.60	3.58	1.17	10.99
NEUTROPHIL COUNT DECREASED	13	4	4.59	3.58	1.17	10.98	13	4	4.60	3.58	1.17	10.99
VISUAL ACUTY REDUCED	28	14	5.39	2.20	1.16	4.18	28	14	5.40	2.20	1.16	4.19
TONGUE MOVEMENT	22	10	4.93	2.42	1.15	5.12	21	10	4.28	2.32	1.09	4.92
DISURBANCE	19	8	4.74	2.62	1.15	5.98	19	8	4.75	2.62	1.15	5.98
BREAST INDURATION	19	8	4.74	2.62	1.15	5.98	19	8	4.75	2.62	1.15	5.98
ENDOMETRIAL THICKENING	16	6	4.61	2.94	1.15	7.51	16	6	4.62	2.94	1.15	7.51
ILLUSION	16	6	4.61	2.94	1.15	7.51	16	6	4.62	2.94	1.15	7.51
TOOTH EXTRACTION	16	6	4.61	2.94	1.15	7.51	16	6	4.62	2.94	1.15	7.51
ALANINE AMINOTRANSFERASE INCREASED	33	18	5.33	2.02	1.14	3.59	33	18	5.34	2.02	1.14	3.59
LIVER DISORDER	30	16	5.05	2.07	1.13	3.70	30	16	5.06	2.07	1.13	3.79
MUSCLE INJURY	26	13	4.95	2.20	1.13	4.29	26	13	4.97	2.20	1.13	4.29
GLUTEN SENSITIVITY	11	3	4.22	4.04	1.13	14.48	11	3	4.23	4.04	1.13	14.49
LABILE BLOOD PRESSURE	11	3	4.22	4.04	1.13	14.48	11	3	4.23	4.04	1.13	14.49
PAROTID GLAND ENLARGEMENT	23	11	4.71	2.30	1.12	4.72	23	11	4.72	2.31	1.12	4.73
INTRACRANIAL PRESSURE INCREASED	20	9	4.49	2.45	1.11	5.38	20	8	5.47	2.76	1.21	6.36
ATTENTION DEFICIT	17	7	4.31	2.67	1.11	6.45	17	7	4.32	2.68	1.11	6.46
HYPERACTIVITY DISORDER	14	5	4.19	3.08	1.11	8.56	14	5	4.20	3.09	1.11	8.57
ANAL HAE MORRAGE	14	5	4.19	3.08	1.11	8.56	14	5	4.20	3.09	1.11	8.57
IMMUNISATION ANXIETY RELATED REACTION	14	5	4.19	3.08	1.11	8.56	14	5	4.20	3.09	1.11	8.57

BRIDOCYCLITIS	21	10	4.27	2.31	1.09	4.91	21	10	4.28	2.32	1.09	4.92
OVERSENSING	21	10	4.27	2.31	1.09	4.91	21	10	4.28	2.32	1.09	4.92
THYROID PAIN	21	10	4.27	2.31	1.09	4.91	21	10	4.28	2.32	1.09	4.92
SOMNAMBULISM	18	8	4.03	2.48	1.08	5.70	18	8	4.06	2.48	1.08	5.70
HEAVY MENSTRUAL BLEEDING	2610	1432	470.21	2.01	1.88	2.14	2599	1433	464.10	2.00	1.87	2.13
ACUTE KIDNEY INJURY	44	24	7.32	2.02	1.33	3.32	41	23	6.34	1.97	1.18	3.27
ACUTE RESPIRATORY FAILURE	16	6	4.61	2.94	1.15	7.51	15	6	3.89	2.76	1.07	7.10
SPTUM INCREASED	11	3	4.22	4.04	1.13	14.48	10	3	3.39	3.67	1.01	13.55
PATIENT ISOLATION	14	5	4.19	3.08	1.11	8.56	13	5	3.46	2.87	1.02	8.04
BODY HEIGHT DECREASED	50	1	50.05	55.07	7.61	398.64	50	1	50.10	55.12	7.61	399.00
SALIVARY GLAND PAIN	17	2	11.74	9.26	2.16	40.52	17	2	11.75	9.37	2.16	40.56
PIARYNGEAL INFLAMMATION	15	2	9.69	8.26	1.89	36.12	15	2	9.70	8.27	1.89	36.15
LYMPHOCYTE COUNT	12	1	8.71	13.22	1.72	101.64	12	1	8.72	13.23	1.72	101.74
DECREASED	12	2	6.70	6.61	1.48	29.53	12	2	6.71	6.61	1.48	29.55
VENOUS THROMBOSIS	10	1	6.63	11.01	1.41	86.04	10	1	6.64	11.02	1.41	86.12
BRAIN NEOPLASM	10	1	6.63	11.01	1.41	86.04	10	1	6.64	11.02	1.41	86.12
HYPOAESTHESIA TEETH	10	1	6.63	11.01	1.41	86.04	10	1	6.64	11.02	1.41	86.12
GESTATIONAL DIABETES	11	2	5.74	6.06	1.34	27.33	11	2	5.75	6.06	1.34	27.35
INFLAMMATORY MARKER	9	1	5.61	9.91	1.26	78.24	8	1	4.62	8.82	1.10	70.51
POTENTIATING DRUG	9	1	5.61	9.91	1.26	78.24	9	1	5.62	9.92	1.26	78.31
INTERACTION	9	1	5.61	9.91	1.26	78.24	9	1	5.62	9.92	1.26	78.31
THERAPEUTIC RESPONSE	9	1	5.61	9.91	1.26	78.24	9	1	5.62	9.92	1.26	78.31
SHORTENED	9	1	5.61	9.91	1.26	78.24	9	1	5.62	9.92	1.26	78.31
WOUND DRAINAGE	10	2	4.80	5.51	1.21	25.13	10	2	4.81	5.51	1.21	25.16
BRAIN INJURY	10	2	4.80	5.51	1.21	25.13	10	2	4.81	5.51	1.21	25.16
CLONUS	10	2	4.80	5.51	1.21	25.13	10	2	4.81	5.51	1.21	25.16
CYST RUPTURE	10	2	4.80	5.51	1.21	25.13	10	2	4.81	5.51	1.21	25.16
HYPOMAGNESEMIA	10	2	4.80	5.51	1.21	25.13	10	2	4.81	5.51	1.21	25.16
ALOPECIA UNIVERSALIS	8	1	4.61	8.81	1.10	70.45	8	1	4.62	8.82	1.10	70.51
CEREBROSPINAL FLUID	8	1	4.61	8.81	1.10	70.45	8	1	4.62	8.82	1.10	70.51
CHRONIC PIGMENTED PURPURA	8	1	4.61	8.81	1.10	70.45	8	1	4.62	8.82	1.10	70.51
VENTRICULAR ARRHYTHMIA	8	1	4.61	8.81	1.10	70.45	8	1	4.62	8.82	1.10	70.51
EUSTACHIAN TUBE	8	1	4.61	8.81	1.10	70.45	8	1	4.62	8.82	1.10	70.51
OBSTRUCTION	8	1	4.61	8.81	1.10	70.45	7	1	3.64	7.72	0.95	62.72
BLOOD CHOLESTEROL	54	30	8.73	1.98	1.27	3.10	54	28	10.28	2.13	1.35	3.36
INCREASED	6	1	2.69	6.61	0.80	54.89	6	0				
BLOOD TRIGLYCERIDES	6	1	2.69	6.61	0.80	54.89	6	0				
INCREASED	6	1	2.69	6.61	0.80	54.89	6	0				

PREFERRED Medical Dictionary for Regulatory Activities (MedDRA) Terms (VAERS-1 Box 7, VAERS 2.0 Box 18)

For Current Week and Past Week Comparison

Following **ALL 12/14/2020-04/22/2022 COVID19 Pfizer Ages 18+ Vaccines**

Compared to **ALL 12/14/2020-04/22/2022 COVID19 Moderna Ages 18+ Vaccines**

AGES 18+ YEARS, Initial domestic reports only, VAERS reports as of 04/22/2022

Vaccination, Received, and Completed Date: 12/14 - 04/22 (Current Week) and 12/14 - 04/15 (Past Week)

N $\geq$ 3 (Current Week), PRR $\geq$ 2.00 (Ratio of Proportions), Chi-Square $\geq$ 4.00

MedDRA PTs sorting based on lower confidence limit and PFIZER adverse event count from 12/14/2020-04/22/2022

AGES 18+ YEARS excludes missing ages

MedDRA Codes ALL Reports (18+)	12/14/2020- 04/22/2022 PFIZER N=303997	12/14/2020- 04/22/2022 MODERNA N=324518	12/14-04/22 Chi-Square	12/14-04/22 PRR	12/14-04/22 LCL	12/14-04/22 UCL	12/14/2020- 04/15/2022 PFIZER N=303122	12/14/2020- 04/15/2022 MODERNA N=323433	12/14-04/15 Chi-Square	12/14-04/15 PRR	12/14-04/15 LCL	12/14-04/15 UCL
PRODUCT PREPARATION ERROR	561	15	552.97	39.92	23.91	66.67	560	15	551.63	39.83	23.85	66.52
VACCINATION FAILURE	1006	60	903.07	17.90	13.79	23.22	977	54	887.78	19.30	14.68	25.39
PRODUCT PREPARATION ISSUE	2102	166	1788.02	13.52	11.54	15.83	2105	166	1790.23	13.53	11.55	15.85
DISEASE RECURRENCE	216	11	197.17	20.96	11.44	38.42	216	11	197.07	20.95	11.43	38.40
PRODUCT USE ISSUE	437	29	383.24	16.09	11.05	23.42	432	27	382.95	17.07	11.57	25.18
IMMUNISATION	2523	215	2108.84	12.53	10.90	14.40	2517	215	2101.41	12.49	10.87	14.36
OFF LABEL USE	986	211	553.94	4.99	4.30	5.79	973	211	541.30	4.92	4.24	5.71
CIRCUMSTANCE OR INFORMATION CAPABLE OF LEADING TO MEDICATION ERROR	124	19	82.60	6.97	4.30	11.29	124	17	86.82	7.78	4.69	12.92
IMMUNODEFICIENCY	483	112	255.39	4.60	3.75	5.65	481	108	260.20	4.75	3.86	5.85
DRUG INEFFECTIVE	1061	272	520.36	4.16	3.65	4.76	1023	267	493.72	4.09	3.57	4.68
APPARENT LIFE THREATENING EVENT	64	10	41.55	6.83	3.51	13.30	64	10	41.52	6.83	3.51	13.30
INCORRECT PRODUCT FORMULATION ADMINISTERED	547	162	234.32	3.60	3.03	4.29	548	162	234.99	3.61	3.03	4.30
MIDDLE INSOMNIA	77	17	41.03	4.84	2.86	8.18	75	17	39.15	4.71	2.78	7.97
OVERDOSE	177	56	69.99	3.37	2.50	4.56	176	56	69.10	3.35	2.48	4.53
WHITE BLOOD CELL COUNT INCREASED	113	37	42.61	3.26	2.25	4.73	113	37	42.58	3.26	2.25	4.72
NEAR DEATH EXPERIENCE	108	35	41.16	3.29	2.25	4.82	106	35	39.49	3.23	2.21	4.74
INTERCHANGE OF VACCINE PRODUCTS	5790	2644	1407.48	2.34	2.23	2.45	5788	2638	1410.30	2.34	2.24	2.45
CROHN'S DISEASE	128	47	42.04	2.91	2.08	4.06	126	45	42.85	2.99	2.13	4.20
ANTINUCLEAR ANTIBODY POSITIVE	30	7	14.57	4.58	2.01	10.42	30	7	14.56	4.57	2.01	10.41
SKIN DISORDER	272	120	68.56	2.42	1.95	3.00	267	118	67.01	2.41	1.94	3.00
EXPOSURE TO SARS-COV-2	1251	629	248.69	2.12	1.93	2.34	1236	622	244.92	2.12	1.93	2.33
DRUG HYPERSENSITIVITY	181	77	48.19	2.51	1.92	3.28	181	74	51.28	2.61	1.99	3.42
POLYMERIZATION	462	220	101.85	2.24	1.91	2.63	462	219	102.62	2.25	1.92	2.64
UTERINE HAEMORRHAGE	64	22	22.34	3.11	1.91	5.04	64	22	22.32	3.10	1.91	5.04
EAR DISORDER	111	44	32.62	2.69	1.90	3.82	108	42	32.58	2.74	1.92	3.92
MENSTRUAL DISORDER	1598	829	297.23	2.06	1.89	2.24	1594	830	293.63	2.05	1.88	2.23
CLAUSTROPHOBIA	23	5	11.47	4.91	1.87	12.92	23	5	11.47	4.91	1.87	12.91
INTERMENSTRUAL BLEEDING	866	449	160.68	2.06	1.84	2.31	866	447	162.06	2.07	1.84	2.32
HYPOMENORRHOEA	116	49	30.93	2.53	1.81	3.53	116	48	31.93	2.58	1.84	3.61
STRIDOR	124	54	31.49	2.45	1.78	3.37	123	54	30.76	2.43	1.76	3.35
VIBRATORY SENSE INCREASED	66	25	30.32	2.82	1.78	4.47	63	24	19.18	2.80	1.75	4.48
PHARYNGEAL INFLAMMATION	17	3	9.33	6.05	1.77	20.64	17	3	9.32	6.05	1.77	20.63
BONE DISORDER	40	13	14.53	3.28	1.76	6.14	40	13	14.51	3.28	1.76	6.14

ELCTROCARDIOGRAM	77	31	21.83	2.65	1.75	4.02	77	31	21.81	2.65	1.75	4.02
ABNORMAL												
BLOOD LACTIC ACID	19	4	9.47	5.07	1.73	14.90	18	4	8.56	4.80	1.63	14.19
INCREASED												
UPPER RESPIRATORY TRACT	101	44	25.47	2.45	1.72	3.49	101	43	26.44	2.51	1.75	3.58
CONGESTION	410	217	72.15	2.02	1.71	2.38	407	217	70.30	2.00	1.70	2.36
APPENDICITIS	71	29	19.63	2.61	1.70	4.03	71	29	19.60	2.61	1.70	4.02
HAEMOGLOBIN DECREASED	140	66	30.90	2.26	1.69	3.03	137	66	28.93	2.21	1.65	2.97
NERVE COMPRESSION												
MAST CELL ACTIVATION	49	18	15.48	2.91	1.69	4.99	49	18	15.47	2.90	1.69	4.99
SYNDROME	100	45	21.82	2.37	1.67	3.37	99	45	23.12	2.35	1.65	3.34
FIBRIN D DIMER INCREASED												
VACCINATION SITE	50	19	15.09	2.81	1.66	4.76	49	19	14.34	2.75	1.62	4.67
HYPOALBEMIA	44	16	13.99	2.94	1.66	5.20	44	16	13.98	2.93	1.66	5.20
NORMAL LABOUR	16	3	8.39	5.69	1.66	19.54	16	3	8.39	5.69	1.66	19.53
ANGIOGRAM	71	30	18.58	2.53	1.65	3.87	72	30	19.27	2.56	1.67	3.92
FACIAL SPASM	25	7	10.19	3.81	1.65	8.81	24	7	9.81	3.66	1.58	8.49
WEIGHT FLUCTUATION	29	9	10.79	3.44	1.63	7.27	29	9	10.78	3.44	1.63	7.26
LIVE BIRTH	33	11	11.45	3.20	1.63	6.34	33	11	11.44	3.20	1.62	6.33
PERITONITIS												
BASEDOW'S DISEASE	91	42	20.63	2.31	1.60	3.33	91	42	20.60	2.31	1.60	3.33
WHITE BLOOD CELL COUNT												
DECREASED	59	25	15.23	2.52	1.58	4.02	59	24	16.24	2.62	1.63	4.22
WOUND DRAINAGE	24	7	9.35	3.66	1.58	8.49	23	7	8.51	3.51	1.50	8.17
BODY TEMPERATURE												
ABNORMAL	115	57	21.83	2.15	1.57	2.96	115	55	24.51	2.23	1.62	3.08
SUPPRESSED LACTATION	89	42	19.32	2.26	1.57	3.26	89	42	19.30	2.26	1.57	3.26
CEREBROVASCULAR DISORDER	36	13	11.38	2.96	1.57	5.57	35	12	11.79	3.11	1.62	6.00
RED BLOOD CELL COUNT												
DECREASED	30	10	10.32	3.20	1.57	6.55	30	10	10.31	3.20	1.56	6.55
BLOOD CHOLESTEROL												
INCREASED	78	36	17.57	2.31	1.56	3.43	78	36	17.55	2.31	1.56	3.43
PIARYNGEAL MASS	15	3	7.47	5.34	1.55	18.44	15	3	7.46	5.34	1.54	18.43
PNEUMONIA PSEUDOMONAL	15	3	7.47	5.34	1.55	18.44	15	3	7.46	5.34	1.54	18.43
ENDOTRACHEAL INTUBATION												
COMPLICATION	17	4	7.67	4.54	1.53	13.48	17	4	7.67	4.53	1.53	13.48
APPENDICITIS PERFORATED	76	36	16.27	2.25	1.52	3.35	76	36	16.25	2.25	1.52	3.35
ABNORMAL UTERINE BLEEDING	57	25	13.85	2.43	1.52	3.89	57	25	13.83	2.43	1.52	3.89
OSTEOPENIA	35	13	10.62	2.87	1.52	5.43	35	13	10.61	2.87	1.52	5.43
LACTATION DISORDER	33	12	10.25	2.94	1.52	5.68	33	12	10.24	2.93	1.52	5.68
CONVALESCENT PLASMA												
TRANSFUSION	44	18	11.79	2.61	1.51	4.52	44	18	11.78	2.61	1.51	4.51
RENAL TRANSPLANT	21	6	8.21	3.74	1.51	9.26	21	6	8.20	3.73	1.51	9.25
PUPILLARY REFLEX IMPAIRED	65	30	14.51	2.31	1.50	3.56	64	29	14.75	2.35	1.52	3.65
BLOOD BILIRUBIN INCREASED	25	8	8.85	3.34	1.50	7.40	25	8	8.84	3.33	1.50	7.39
GASTRIC DISORDER	102	53	18.19	2.05	1.47	2.86	101	51	19.16	2.11	1.51	2.96
OVARIAN CYST	95	49	17.18	2.07	1.47	2.92	94	49	16.56	2.05	1.45	2.89
COMA SCALE ABNORMAL	74	36	15.00	2.19	1.47	3.27	74	36	13.74	2.13	1.43	3.18
BLADDER DISORDER	53	24	12.11	2.36	1.46	3.82	53	24	12.09	2.36	1.45	3.82
RTD BLOOD CELL												
SEDIMENTATION RATE												
INCREASED	37	15	9.92	2.63	1.45	4.80	36	14	10.25	2.74	1.48	5.09
VENTRICULAR ARRHYTHMIA	26	9	8.41	3.08	1.45	6.58	26	8	9.65	3.47	1.57	7.66
AUTONOMIC NERVOUS SYSTEM												
IMBALANCE	93	49	16.00	2.03	1.43	2.86	92	48	16.16	2.05	1.44	2.90
MASTITIS	67	33	13.17	2.17	1.43	3.29	67	33	13.15	2.17	1.43	3.29
HANGOVER	59	28	12.41	2.25	1.43	3.53	59	28	12.40	2.25	1.43	3.53
CIRCUMEN IMPACTION	20	6	7.38	3.56	1.43	8.86	20	6	7.38	3.56	1.43	8.86

MAGNETIC RESONANCE IMAGING HEART	20	6	7.38	3.56	1.43	8.86	20	6	7.38	3.56	1.43	8.86
PHARYNGEAL DISORDER	20	6	7.38	3.56	1.43	8.86	20	6	7.38	3.56	1.43	8.86
AORTIC DISORDER	18	5	7.08	3.84	1.43	10.35	18	5	7.07	3.84	1.43	10.35
HEMIANAESTHESIA	18	5	7.08	3.84	1.43	10.35	18	5	7.07	3.84	1.43	10.35
NEUTROPHIL COUNT DECREASED	16	4	6.80	4.27	1.43	12.77	16	4	6.79	4.27	1.43	12.77
COLOSTOMY	14	3	6.56	4.98	1.43	17.33	14	3	6.56	4.98	1.43	17.33
SLEEP DISORDER DUE TO A GENERAL MEDICAL CONDITION	14	3	6.56	4.98	1.43	17.33	14	3	6.56	4.98	1.43	17.33
NASAL PRURITUS	58	28	11.78	2.21	1.41	3.47	58	28	11.76	2.21	1.41	3.47
VOCAL CORD PARALYSIS	29	11	8.39	2.81	1.41	5.63	28	9	9.97	3.32	1.57	7.03
ANKYLOSING SPONDYLITIS	27	10	8.01	2.88	1.40	5.95	26	10	7.27	2.77	1.34	5.75
C-REACTIVE PROTEIN INCREASED	57	28	11.16	2.17	1.38	3.42	57	26	12.89	2.34	1.47	3.72
WRONG PATIENT	32	13	8.43	2.63	1.38	5.01	32	13	8.42	2.63	1.38	5.00
SUBMAXILLARY GLAND ENLARGEMENT	25	9	7.64	2.97	1.38	6.35	25	9	7.63	2.96	1.38	6.35
BASAL GANGLIA INFARCTION	28	11	7.66	2.72	1.35	5.46	28	10	8.76	2.99	1.45	6.15
NONINFECTIVE ENCEPHALITIS	38	11	7.66	2.72	1.35	5.46	28	11	7.65	2.72	1.35	5.46
VIRAL SEPSIS	19	6	6.58	3.38	1.35	8.46	19	5	7.92	4.05	1.51	10.86
PHARYNGITIS STREPTOCOCCAL	60	31	10.55	2.07	1.34	3.19	57	30	9.56	2.03	1.30	3.15
PROTEINURIA	60	31	10.55	2.07	1.34	3.19	60	31	10.54	2.07	1.34	3.19
INTRACRANIAL PRESSURE INCREASED	41	19	8.80	2.30	1.34	3.97	40	19	8.15	2.25	1.30	3.88
HORMONE LEVEL ABNORMAL	64	34	10.59	2.01	1.33	3.05	64	34	10.58	2.01	1.33	3.04
FEBRILE NEUTROPENIA	36	16	8.25	2.40	1.33	4.33	36	16	8.23	2.40	1.33	4.33
MEASLES	15	4	5.94	4.00	1.33	12.06	15	4	5.94	4.00	1.33	12.06
PARENTERAL NUTRITION	15	4	5.94	4.00	1.33	12.06	15	4	5.94	4.00	1.33	12.06
THYROIDITIS	50	25	9.34	2.14	1.32	3.45	50	25	9.33	2.13	1.32	3.45
STILLBIRTH	39	18	8.39	2.31	1.32	4.04	39	18	8.38	2.31	1.32	4.04
DECREASED NASOLABIAL FOLD	24	9	6.90	2.85	1.32	6.12	24	9	6.89	2.85	1.32	6.12
PHARYNGEAL ULCERATION	24	9	6.90	2.85	1.32	6.12	23	8	7.27	3.07	1.37	6.86
GESTATIONAL DIABETES	22	8	6.52	2.94	1.31	6.59	22	8	6.51	2.93	1.31	6.59
NAIL DISCOLOURATION	60	32	9.80	2.00	1.30	3.07	60	31	10.54	2.07	1.34	3.19
TIC	49	25	8.74	2.09	1.29	3.39	49	25	8.73	2.09	1.29	3.39
OCULAR ICTERUS	38	18	7.76	2.25	1.29	3.95	37	18	7.12	2.19	1.25	3.85
HEARING AID USER	35	16	7.59	2.34	1.29	4.22	31	16	5.13	2.07	1.13	3.78
BLOOD THYROID STIMULATING HORMONE INCREASED	30	13	7.05	2.46	1.29	4.72	30	13	7.04	2.46	1.28	4.72
VISUAL ACUTY REDUCED	50	26	8.55	2.05	1.28	3.30	50	26	8.54	2.05	1.28	3.30
ENDOMETRIAL THICKENING	25	10	6.56	2.67	1.28	5.56	25	10	6.55	2.67	1.28	5.55
AZOTAFEMIA	39	19	7.54	2.19	1.27	3.79	39	18	8.38	2.31	1.32	4.04
PETIT MAL EPILEPSY	28	12	6.65	2.49	1.27	4.90	28	12	6.65	2.49	1.27	4.90
LABILE BLOOD PRESSURE	18	6	5.79	3.20	1.27	8.07	18	6	5.79	3.20	1.27	8.06
DYSAESTHESIA	37	18	7.13	2.19	1.25	3.85	37	18	7.12	2.19	1.25	3.85
FACTOR V LEIDEN MUTATION	16	5	5.44	3.42	1.25	9.32	16	5	5.44	3.41	1.25	9.32
COPULMONALE	21	8	5.79	2.80	1.24	6.33	20	8	5.07	2.67	1.17	6.06
UTERINE PAIN	38	19	6.93	2.14	1.23	3.70	38	19	6.92	2.13	1.23	3.70
ANTIALLERGIC THERAPY	32	15	6.55	2.28	1.23	4.21	32	15	6.54	2.28	1.23	4.20
BLOOD SODIUM DECREASED	24	10	5.86	2.56	1.23	5.36	24	10	5.86	2.56	1.22	5.35
HAEMOTHORAX	14	4	5.11	3.74	1.23	11.35	14	4	5.11	3.73	1.23	11.35
POSTPARTUM STATE	14	4	5.11	3.74	1.23	11.35	13	4	4.31	3.47	1.13	10.64
THERAPEUTIC PRODUCT EFFECT DECREASED	14	4	5.11	3.74	1.23	11.35	13	4	4.31	3.47	1.13	10.64

WOUND INFECTION	27	12	5.99	2.40	1.22	4.74	26	11	6.25	2.52	1.25	5.10
ESCHERICHIA URINARY TRACT INFECTION	19	7	5.41	2.90	1.22	6.89	19	7	5.40	2.90	1.22	6.89
POSTPARTUM HAEMORRHAGE	19	7	5.41	2.90	1.22	6.89	19	7	5.40	2.90	1.22	6.89
VERTEBRAL ARTERY DISSECTION	19	7	5.41	2.90	1.22	6.89	19	7	5.40	2.90	1.22	6.89
WALKING DISABILITY	33	16	6.33	2.20	1.21	4.00	33	16	6.32	2.20	1.21	4.00
CARDIAC VALVE DISEASE	30	14	6.15	2.29	1.21	4.31	30	13	7.04	2.46	1.28	4.72
ALANINE AMINOTRANSFERASE INCREASED	40	21	6.56	2.03	1.20	3.45	40	21	6.55	2.03	1.20	3.45
SICK RELATIVE	37	19	6.34	2.08	1.20	3.61	37	19	6.33	2.08	1.20	3.61
RENAL MASS	22	9	5.47	2.61	1.20	5.67	22	9	5.46	2.61	1.20	5.66
FOETAL HYPOKINESIA	34	17	6.13	2.14	1.19	3.82	34	17	6.12	2.13	1.19	3.82
NIH STROKE SCALE	34	17	6.13	2.14	1.19	3.82	34	16	6.94	2.27	1.25	4.11
PLATELET COUNT INCREASED	31	15	5.93	2.21	1.19	4.09	31	14	6.78	2.36	1.26	4.44
EYE OEDEMA	25	11	5.59	2.43	1.19	4.93	25	10	6.55	2.67	1.28	5.55
PROTEIN URINE PRESENT	17	6	5.03	3.02	1.19	7.67	17	6	5.03	3.02	1.19	7.67
ELECTROCARDIOGRAM ST SEGMENT ABNORMAL	35	18	5.94	2.08	1.18	3.66	34	16	6.94	2.27	1.25	4.11
MENINGITIS VIRAL	20	8	5.08	2.67	1.18	6.06	20	8	5.07	2.67	1.17	6.06
MUSCLE RUPTURE	20	8	5.08	2.67	1.18	6.06	19	8	4.39	2.53	1.11	5.79
NECROSIS	20	8	5.08	2.67	1.18	6.06	19	8	4.39	2.53	1.11	5.79
MENISCUS INJURY	26	12	5.34	2.31	1.17	4.58	24	12	4.12	2.13	1.07	4.27
PELVIC VENOUS THROMBOSIS	26	12	5.34	2.31	1.17	4.58	26	12	5.34	2.31	1.17	4.58
ABDOMINAL MASS	23	10	5.19	2.46	1.17	5.16	23	10	5.18	2.45	1.17	5.16
INCORRECT PRODUCT ADMINISTRATION DURATION	23	10	5.19	2.46	1.17	5.16	23	10	5.18	2.45	1.17	5.16
PHONOPHOBIA	23	10	5.19	2.46	1.17	5.16	23	10	5.18	2.45	1.17	5.16
COMPLICATED APPENDICITIS	15	5	4.66	3.20	1.16	8.81	15	5	4.66	3.20	1.16	8.81
COMPUTERISED TOMOGRAM THORAX	15	5	4.66	3.20	1.16	8.81	15	5	4.66	3.20	1.16	8.81
PNEUMOMEDIASTINUM	33	17	5.54	2.07	1.15	3.72	33	17	5.53	2.07	1.15	3.72
HEPATIC MASS	30	15	5.32	2.14	1.15	3.97	30	15	5.32	2.13	1.15	3.97
RED BLOOD CELL TRANSFUSION	30	15	5.32	2.14	1.15	3.97	29	12	7.33	2.58	1.32	5.05
ACUTE CARDIAC EVENT	27	13	5.12	2.22	1.14	4.30	27	11	6.94	2.62	1.30	5.28
CORONARY ANGIOPLASTY	27	13	5.12	2.22	1.14	4.30	27	12	5.98	2.40	1.22	4.74
HYPOSMOLAR STATE	27	13	5.12	2.22	1.14	4.30	27	13	5.12	2.22	1.14	4.29
PATIENT UNCOOPERATIVE	27	13	5.12	2.22	1.14	4.30	27	13	5.12	2.22	1.14	4.29
PENILE PAIN	13	4	4.31	3.47	1.13	10.64	13	4	4.31	3.47	1.13	10.64
DEPERSONALISATION/DEREALISATION DISORDER	28	14	4.92	2.14	1.12	4.06	29	13	6.38	2.38	1.24	4.58
BLOOD CREATINE PHOSPHOKINASE INCREASED	25	12	4.72	2.22	1.12	4.43	24	12	4.12	2.13	1.07	4.27
LABORATORY TEST ABNORMAL	29	15	4.74	2.06	1.11	3.85	29	15	4.74	2.06	1.11	3.85
MICROCYTIC ANAEMIA	29	15	4.74	2.06	1.11	3.85	29	15	4.74	2.06	1.11	3.85
THYROID PAIN	22	10	4.54	2.35	1.11	4.96	22	10	4.53	2.35	1.11	4.96
ORTHOSTATIC HYPERTENSION	19	8	4.39	2.54	1.11	5.79	19	8	4.39	2.53	1.11	5.79
BLOOD POTASSIUM INCREASED	16	6	4.30	2.85	1.11	7.27	16	6	4.29	2.85	1.11	7.27
CIRRHOSIS ALCOHOLIC	16	6	4.30	2.85	1.11	7.27	16	6	4.29	2.85	1.11	7.27
CLONUS	26	13	4.52	2.14	1.10	4.15	27	13	5.12	2.22	1.14	4.29
INTESTINAL PERFORATION	26	13	4.52	2.14	1.10	4.15	25	11	5.58	2.43	1.19	4.93
BRONCHIAL SECRETION RETENTION	30	16	4.58	2.00	1.09	3.67	29	15	4.74	2.06	1.11	3.85

ALCOHOL WITHDRAWAL SYNDROME	23	11	4.33	2.23	1.09	4.58	23	11	4.31	2.23	1.09	4.58
HIDRADENITIS	23	11	4.32	2.23	1.09	4.58	23	11	4.31	2.23	1.09	4.58
MITRAL VALVE CALCIFICATION	23	11	4.32	2.23	1.09	4.58	23	11	4.31	2.23	1.09	4.58
NIH STROKE SCALE SCORE INCREASED	27	14	4.34	2.06	1.08	3.93	27	14	4.34	2.06	1.08	3.92
ILLUSION	20	9	4.14	2.37	1.08	5.21	20	9	4.13	2.37	1.08	5.21
SOCIAL AVOIDANT BEHAVIOUR	20	9	4.14	2.37	1.08	5.21	20	9	4.13	2.37	1.08	5.21
CEREBRAL ARTERY STENOSIS	24	12	4.12	2.14	1.07	4.27	24	12	4.12	2.13	1.07	4.27
SUSPECTED COVID-19	341	182	58.72	2.00	1.67	2.39	331	181	53.66	1.95	1.63	2.34
DELIVERY	200	106	34.72	2.01	1.59	2.55	193	105	31.40	1.96	1.55	2.49
COLECTOMY	40	21	6.56	2.03	1.20	3.45	39	21	5.99	1.98	1.17	3.37
MORPHOEA	12	3	4.81	4.27	1.20	15.13	11	3	3.97	3.91	1.09	14.02
LANGUAGE DISORDER	24	11	4.94	2.33	1.14	4.75	22	11	3.72	2.13	1.03	4.40
LABOUR INDUCTION	28	14	4.92	2.14	1.12	4.06	26	14	3.78	1.98	1.03	3.79
APPENDIX DISORDER	16	6	4.30	2.85	1.11	7.27	15	6	3.59	2.67	1.04	6.87
TOOTH EXTRACTION	26	13	4.52	2.14	1.10	4.15	25	13	3.94	2.05	1.05	4.01
ENDOMETRIOSIS	27	14	4.34	2.06	1.08	3.93	26	14	3.78	1.98	1.03	3.79
BODY HEIGHT DECREASED	55	2	50.95	29.36	7.16	120.35	55	2	50.93	29.34	7.16	120.29
PRODUCT LOT NUMBER ISSUE	25	1	21.90	26.69	3.62	196.95	25	1	21.89	26.68	3.61	196.86
PNEUMOTHORAX												
SPONTANEOUS	18	2	12.26	9.61	2.23	41.41	17	2	11.26	9.07	2.10	39.25
SALIVARY GLAND PAIN	18	2	12.26	9.61	2.23	41.41	18	2	12.26	9.60	2.23	41.39
ELDERLY	13	2	7.34	6.94	1.57	30.75	13	2	7.34	6.94	1.57	30.73
LYMPHOCYTE COUNT DECREASED	13	2	7.34	6.94	1.57	30.75	13	2	7.34	6.94	1.57	30.73
OCULAR VASCULAR DISORDER	13	2	7.34	6.94	1.57	30.75	13	2	7.34	6.94	1.57	30.73
CEREBROSPINAL FLUID LEAKAGE	11	1	7.36	11.74	1.52	90.95	11	1	7.35	11.74	1.52	90.91
CYST RUPTURE	12	2	6.40	6.41	1.43	28.62	12	2	6.39	6.40	1.43	28.60
HYPOAESTHESIA TEETH	12	2	6.40	6.41	1.43	28.62	12	2	6.39	6.40	1.43	28.60
INTERVERTEBRAL DISCITIS	12	2	6.40	6.41	1.43	28.62	12	2	6.39	6.40	1.43	28.60
MENORRHAGIA	12	2	6.40	6.41	1.43	28.62	12	2	6.39	6.40	1.43	28.60
ALOPECIA UNIVERSALIS	10	1	6.36	10.68	1.37	83.39	10	1	6.36	10.67	1.37	83.35
ENTEROBACTER INFECTION	10	1	6.36	10.68	1.37	83.39	10	1	6.36	10.67	1.37	83.35
THERAPEUTIC RESPONSE SHORTENED	10	1	6.36	10.68	1.37	83.39	10	1	6.36	10.67	1.37	83.35
ACUTE STRESS DISORDER	11	2	5.47	5.87	1.30	26.49	11	2	5.46	5.87	1.30	26.48
MUTISM	11	2	5.47	5.87	1.30	26.49	11	2	5.46	5.87	1.30	26.48
CHRONIC PIGMENTED PURPURA	9	1	5.37	9.61	1.22	75.83	9	1	5.37	9.60	1.22	75.80
GASTRITIS EROSIVE	9	1	5.37	9.61	1.22	75.83	9	1	5.37	9.60	1.22	75.80
SCIATIC NERVE INJURY	9	1	5.37	9.61	1.22	75.83	8	1	4.40	8.54	1.07	68.25
BLOOD MAGNESIUM DECREASED	10	2	4.56	5.34	1.17	24.36	11	2	4.56	5.87	1.30	26.48
ECHOCARDIOGRAM ABNORMAL	10	2	4.56	5.34	1.17	24.36	10	2	4.55	5.34	1.17	24.35
LOW DENSITY LIPOPROTEIN INCREASED	10	2	4.56	5.34	1.17	24.36	10	2	4.55	5.34	1.17	24.35
PERICARDIAL DISEASE	10	2	4.56	5.34	1.17	24.36	10	2	4.55	5.34	1.17	24.35
ANGLE CLOSURE GLAUCOMA	8	1	4.41	8.54	1.07	68.28	8	1	4.40	8.54	1.07	68.25
NEOPLASM PROGRESSION	8	1	4.41	8.54	1.07	68.28	8	1	4.40	8.54	1.07	68.25
POIKILOCYTOSIS	8	1	4.41	8.54	1.07	68.28	8	1	4.40	8.54	1.07	68.25
RED CELL DISTRIBUTION WIDTH INCREASED	8	1	4.41	8.54	1.07	68.28	8	1	4.40	8.54	1.07	68.25
SALIVARY GLAND MASS	8	1	4.41	8.54	1.07	68.28	8	1	4.40	8.54	1.07	68.25
VIRAL PHARYNGITIS	8	1	4.41	8.54	1.07	68.28	8	1	4.40	8.54	1.07	68.25
VEIN DISORDER	87	47	14.06	1.98	1.39	2.82	87	46	14.78	2.02	1.41	2.88

SPINAL DISORDER	31	17	4.43	1.95	1.08	3.52	30	15	5.32	2.13	1.15	3.97
COMPLICATION OF PREGNANCY	17	7	3.99	2.59	1.08	6.25	16	6	4.29	2.85	1.11	7.27
CONVERSION DISORDER	32	18	4.29	1.90	1.07	3.38	32	17	4.96	2.01	1.12	3.62
PROSTATE CANCER	32	18	4.29	1.90	1.07	3.38	31	16	5.13	2.07	1.13	3.78
EPICONDYLITIS	29	16	4.04	1.82	1.05	3.56	30	15	5.32	2.13	1.15	3.97
PNEUMOPERTITONEUM	18	8	3.73	2.40	1.04	5.52	18	7	4.68	2.74	1.15	6.57
CERVICAL RADICULOPATHY	25	14	3.26	1.91	0.99	3.67	24	12	4.12	2.13	1.07	4.27
OBSTRUCTIVE SLEEP APNOEA SYNDROME	9	2	3.68	4.80	1.04	22.23	9	1	5.37	9.60	1.22	75.80

PREFERRED Medical Dictionary for Regulatory Activities (MedDRA) Terms (VAERS-1 Box 7, VAERS 2.0 Box 18)

For Current Week and Past Week Comparison

Following ALL 12/14/2020-04/22/2022 COVID19 Pfizer Ages 18+ Vaccines

Compared to ALL 12/14/2020-04/22/2022 COVID19 Moderna Ages 18+ Vaccines

SERIOUS AGES 18+ YEARS, Initial domestic reports only, VAERS reports as of 04/22/2022

Vaccination, Received, and Completed Date: 12/14 - 04/22 (Current Week) and 12/14 - 04/15 (Past Week)

N>=3 (Current Week), PRR=2.00 (Ratio of Proportions), Chi-Square=4.00

MedDRA PT's sorting based on lower confidence limit and PFIZER adverse event count from 12/14/2020-04/22/2022

SERIOUS AGES 18+ YEARS excludes missing ages

MedDRA Codes ALL Reports (SERIOUS 18+)	12/14/2020- 04/22/2022 PFIZER N=37058	12/14/2020- 04/22/2022 MODERNA N=30309	12/14-04/22 Chi-Square	12/14-04/22 PRR	12/14-04/22 LCL	12/14-04/22 UCL	12/14/2020- 04/15/2022 PFIZER N=36782	12/14/2020- 04/15/2022 MODERNA N=30088	12/14-04/15 Chi-Square	12/14-04/15 PRR	12/14-04/15 LCL	12/14-04/15 UCL
AMUCINATION	133	8	86.67	13.60	6.66	27.75	132	8	85.88	13.50	6.61	27.55
APPARENT LIFE THREATENING EVENT	61	7	31.72	7.13	3.26	35.58	61	7	31.73	7.13	3.26	35.58
VACCINATION FAILURE	67	9	32.45	6.09	3.04	12.21	65	9	30.95	5.91	2.94	11.86
DRUG INEFFECTIVE	110	25	37.24	3.60	2.33	5.55	108	25	35.90	3.53	2.29	5.46
WHITE BLOOD CELL COUNT INCREASED	46	8	18.68	4.70	2.22	9.96	46	8	18.69	4.70	2.22	9.96
DISEASE RECURRENCE	33	5	14.31	5.40	2.11	13.83	33	5	14.31	5.40	2.11	13.83
VIBRATORY SENSE INCREASED	25	3	11.95	6.82	2.06	22.57	24	3	11.20	6.54	1.97	21.73
OFF LABEL USE	75	21	19.83	2.92	1.80	4.74	74	21	19.22	2.88	1.78	4.68
EATING DISORDER	44	12	11.64	3.00	1.58	5.68	44	12	11.64	3.00	1.58	5.68
NEAR DEATH EXPERIENCE	48	16	9.55	2.45	1.39	4.32	47	16	9.01	2.40	1.36	4.24
OSTEOPEXIA	27	7	7.23	3.15	1.37	7.24	27	7	7.23	3.16	1.37	7.24
VERTEBRAL ARTERY DISSECTION	17	3	6.11	4.63	1.36	15.81	17	3	6.11	4.64	1.36	15.82
PERITONITIS	31	9	7.30	2.82	1.34	5.92	31	9	7.30	2.82	1.34	5.92
BLOOD CHOLESTEROL INCREASED	24	6	6.60	3.27	1.34	8.00	24	6	6.60	3.27	1.34	8.00
MOANING	65	26	9.27	2.04	1.30	3.22	64	26	8.81	2.01	1.28	3.18
NORMAL LABOUR	44	16	7.42	2.35	1.37	3.99	44	16	7.43	2.25	1.37	3.99
PHOTOPSIA	47	19	6.37	2.02	1.19	3.45	47	19	6.37	2.02	1.19	3.45
PNEUMONIA PSEUDOMONAL	15	3	4.75	4.09	1.18	14.12	15	3	4.75	4.09	1.18	14.13
ENDOTRACHEAL INTUBATION COMPLICATION	17	4	4.71	3.48	1.17	10.33	17	4	4.71	3.48	1.17	10.33
VOCAL CORD PARALYSIS	17	4	4.71	3.48	1.17	10.33	16	4	4.09	3.27	1.09	9.79
RENAL TRANSPLANT	21	6	4.77	2.86	1.16	7.09	21	6	4.78	2.86	1.16	7.09
MAST CELL ACTIVATION SYNDROME	19	5	4.73	3.11	1.16	8.32	18	5	4.13	2.94	1.09	7.93
PHOTOSENSITIVITY REACTION	25	8	4.93	2.56	1.15	5.67	25	8	4.94	2.56	1.15	5.67
BLOOD DISORDER	24	8	4.39	2.45	1.10	5.46	24	8	4.39	2.45	1.10	5.46
SALIVARY HYPERSECRETION	22	7	4.29	2.57	1.10	6.02	22	7	4.29	2.57	1.10	6.02
COLOSTOMY	14	3	4.09	3.82	1.10	13.28	14	3	4.09	3.82	1.10	13.28
FACIAL SPASM	14	3	4.09	3.82	1.10	13.28	14	3	4.09	3.82	1.10	13.28
MUSCLE FATIGUE	33	13	4.55	2.08	1.09	3.94	33	13	4.55	2.08	1.09	3.94
DECREASED NASOLABIAL FOLD	20	6	4.20	2.73	1.09	6.79	20	6	4.20	2.73	1.10	6.79
BASAL GANGLIA INFARCTION	27	10	4.13	2.21	1.07	4.56	27	9	5.04	2.45	1.15	5.22
BREAST CANCER TUMAL F	32	13	4.09	2.01	1.06	3.84	31	12	4.41	2.11	1.09	4.11
TEMPERATURE INTOLERANCE	50	20	6.98	2.04	1.22	3.43	46	20	5.18	1.88	1.11	3.18
SYMPTOM RECURRENCE	26	9	4.51	2.36	1.11	5.04	25	10	3.18	2.05	0.98	4.26
COMPLICATION OF PREGNANCY	14	3	4.09	3.82	1.10	13.28	13	3	3.46	3.54	1.01	13.44

MATERNAL EXPOSURE BEFORE PREGNANCY	32	13	4.09	2.01	1.06	3.84	31	13	3.64	1.95	1.02	3.73
PRODUCT USE ISSUE	28	2	16.30	11.45	2.73	48.06	28	2	16.30	11.45	2.73	48.07
LIVE BIRTH	21	2	10.82	8.59	2.01	36.62	21	2	10.83	8.59	2.01	36.63
MENISCUS INJURY	15	1	8.30	12.27	1.62	92.87	14	1	7.42	11.45	1.51	87.08
PNEUMOTHORAX												
SPONTANEOUS	17	2	7.78	6.95	1.61	30.09	16	2	7.04	6.54	1.50	28.46
ELDERLY	13	1	6.65	10.63	1.39	81.27	13	1	6.65	10.63	1.39	81.28
CLUSTER HEADACHE	13	2	4.86	5.32	1.20	23.56	13	2	4.86	5.32	1.20	23.56
BODY TEMPERATURE FLUCTUATION	12	2	4.17	4.91	1.10	21.92	12	2	4.17	4.91	1.10	21.93
ENTEROBACTER INFECTION	10	1	4.37	8.18	1.05	63.89	10	1	4.37	8.18	1.05	63.90
VIRAL SEPSIS	19	6	3.64	2.59	1.03	6.48	19	5	4.73	3.11	1.16	8.32
VEIN DISORDER	15	4	3.49	3.07	1.02	9.24	15	3	4.75	4.09	1.18	14.13
EUSTACHIAN TUBE DISORDER	5	1	0.97	4.09	0.48	35.00	5	0	-	-	-	-

PREFERRED Medical Dictionary for Regulatory Activities (MedDRA) Terms (VAERS-1 Box 7, VAERS 2.0 Box 18)

For Current Week and Past Week Comparison

Following **ALL 12/14/2020-04/22/2022 COVID19 Pfizer Ages 18+ Vaccines**

Compared to **ALL 12/14/2020-04/22/2022 COVID19 Moderna Ages 18+ Vaccines**

NON-SERIOUS AGES 18+ YEARS, Initial domestic reports only, VAERS reports as of 04/22/2022

Vaccination, Received, and Completed Date: 12/14 - 04/22 (Current Week) and 12/14 - 04/15 (Past Week)

N>=3 (Current Week), PRR>=2.00 (Ratio of Proportions), Chi-Square>=4.00

MedDRA PTs sorting based on lower confidence limit and PFIZER adverse event count from 12/14/2020-04/22/2022

NON-SERIOUS AGES 18+ YEARS excludes missing ages

MedDRA Codes ALL Reports (NON-SERIOUS 18+)	12/14/2020- 04/22/2022 PFIZER N=266939	12/14/2020- 04/22/2022 MODERNA N=294209	12/14-04/22 Chi-Square	12/14-04/22 PRR	12/14-04/22 LCL	12/14-04/22 UCL	12/14/2020- 04/15/2022 PFIZER N=266340	12/14/2020- 04/15/2022 MODERNA N=293345	12/14-04/15 Chi-Square	12/14-04/15 PRR	12/14-04/15 LCL	12/14-04/15 UCL
PRODUCT PREPARATION ERROR	557	15	567.53	40.93	24.51	68.35	556	15	566.02	40.82	24.45	68.18
VACCINATION FAILURE	939	51	886.92	20.29	15.31	26.90	912	45	872.97	22.32	16.55	30.11
DISEASE RECURRENT	183	6	181.94	33.62	14.91	75.80	183	6	181.80	33.59	14.90	75.75
PRODUCT PREPARATION ISSUE	2099	166	1852.92	13.94	11.90	16.32	2102	166	1854.72	13.95	11.91	16.33
PRODUCT USE ISSUE	409	27	372.17	16.70	11.31	24.64	404	25	371.69	17.80	11.88	26.66
IMMUNISATION	2590	207	2065.94	12.73	11.04	14.67	2385	207	2058.87	12.69	11.01	14.62
IMMUNODEFICIENCY	412	64	288.74	7.10	5.45	9.23	410	61	292.73	7.40	5.66	9.69
OFF LABEL USE	911	190	545.78	5.28	4.52	6.18	899	190	533.43	5.21	4.46	6.09
CIRCUMSTANCE OR INFORMATION CAPABLE OF LEADING TO MEDICATION ERROR	118	19	80.16	6.84	4.22	11.11	118	17	84.25	7.64	4.60	12.71
DRUG INEFFECTIVE	951	247	485.87	4.24	3.69	4.88	915	242	459.87	4.16	3.61	4.80
MIDDLE INSOMNIA	75	15	43.76	5.44	3.12	9.47	72	15	41.76	5.29	3.03	9.22
INCORRECT PRODUCT FORMULATION ADMINISTERED	545	162	246.09	3.71	3.11	4.42	546	162	246.68	3.71	3.12	4.42
OVERDOSE	152	46	66.54	3.64	2.62	5.06	151	46	65.57	3.62	2.60	5.03
INTERCHANGE OF VACCINE PRODUCTS	5730	2582	1543.43	2.45	2.34	2.56	5728	2579	1542.51	2.45	2.34	2.56
CROHN'S DISEASE	94	33	34.57	3.14	2.11	4.67	92	31	35.43	3.27	2.18	4.91
NEAR DEATH EXPERIENCE	60	19	24.39	3.48	2.08	5.83	59	19	23.50	3.42	2.04	5.74
DRUG HYPERSENSITIVITY	149	59	47.35	2.78	2.06	3.76	149	57	49.59	2.88	2.12	3.91
EAR DISORDER	96	35	33.71	3.02	2.05	4.45	94	34	33.27	3.05	2.06	4.51
EXPOSURE TO SARS-COV-2	801	386	188.28	2.29	2.03	2.58	792	383	184.60	2.28	2.02	2.57
SKIN DISORDER	237	102	66.99	2.56	2.03	3.23	232	100	65.29	2.56	2.02	3.23
UTERINE HAEMORRHAGE	56	18	22.33	3.43	2.02	5.83	56	18	22.30	3.43	2.01	5.83
ASYMPTOMATIC COVID-19	334	151	87.41	2.44	2.01	2.95	332	151	85.85	2.42	2.00	2.94
POLYMERORRHOEA	447	209	110.60	2.36	2.00	2.78	447	208	111.36	2.37	2.01	2.79
MENSTRUAL DISORDER	1551	806	314.79	2.12	1.95	2.31	1550	808	311.89	2.11	1.94	2.30
UPPER RESPIRATORY TRACT CONGESTION	93	36	30.14	2.85	1.94	4.18	93	35	31.26	2.93	1.98	4.32
INTERMENSTRUAL BLEEDING	852	437	177.07	2.15	1.92	2.41	852	435	178.43	2.16	1.92	2.42
NERVE COMPRESSION	125	52	36.80	2.65	1.92	3.66	122	52	34.52	2.58	1.87	3.57
STRIDOR	75	28	25.32	2.95	1.91	4.56	75	28	25.29	2.95	1.91	4.55
HYPOMENORRHOEA	114	47	33.94	2.67	1.90	3.75	114	46	34.99	2.73	1.94	3.84
ANTINUCLEAR ANTIBODY POSITIVE	20	4	10.92	5.51	1.88	16.12	20	4	10.90	5.51	1.88	16.11
MENSTRUATION IRREGULAR	2015	1106	362.66	2.01	1.87	2.16	2010	1094	368.14	2.02	1.88	2.18
FIBRIN D DIMER INCREASED	52	18	18.98	3.18	1.86	5.44	52	18	18.95	3.18	1.86	5.44
DYSMENORRHOEA	1137	616	210.08	2.03	1.84	2.24	1134	611	211.74	2.04	1.85	2.26
SUSPECTED COVID-19	264	128	60.72	2.27	1.84	2.81	254	127	54.88	2.20	1.78	2.73
ELECTROCARDIOGRAM ABNORMAL	40	13	15.44	3.39	1.81	6.34	40	13	15.42	3.39	1.81	6.34

REFUSAL OF TREATMENT BY PATIENT	75	31	21.93	2.67	1.75	4.05	75	31	21.89	2.66	1.75	4.05
RED BLOOD CELL COUNT DECREASED	23	6	10.48	4.22	1.72	10.38	23	6	10.46	4.22	1.72	10.37
ANTIALLERGIC THERAPY	16	3	8.81	5.88	1.71	20.17	16	3	8.80	5.87	1.71	20.16
BLOOD THYROID STIMULATING HORMONE INCREASED	27	8	11.12	3.72	1.69	8.19	27	8	11.10	3.72	1.69	8.18
SUPPRESSED LACTATION	89	41	21.92	2.39	1.65	3.46	89	41	21.89	2.39	1.65	3.46
WHITE BLOOD CELL COUNT INCREASED	67	29	18.13	2.55	1.65	3.94	67	29	18.10	2.54	1.65	3.93
GASTRIC DISORDER	88	41	21.23	2.37	1.63	3.43	87	41	20.51	2.34	1.61	3.39
RED BLOOD CELL SEDIMENTATION RATE INCREASED	28	9	10.62	3.43	1.62	7.27	27	8	11.10	3.72	1.69	8.18
MEASLES	15	3	7.85	5.51	1.60	19.04	15	3	7.84	5.51	1.59	19.02
PHARYNGEAL MASS	15	3	7.85	5.51	1.60	19.04	15	3	7.84	5.51	1.59	19.02
WEIGHT FLUCTUATION	15	3	7.85	5.51	1.60	19.04	15	3	7.84	5.51	1.59	19.02
JAW DISORDER	68	31	16.87	2.42	1.58	3.70	68	31	16.84	2.42	1.58	3.69
LACTATION DISORDER	33	12	10.97	3.03	1.57	5.87	33	12	10.95	3.03	1.56	5.86
VACCINATION SITE HYPOAESTHESIA	43	18	12.69	2.69	1.56	4.66	43	18	11.93	2.63	1.52	4.56
MOOD ALTERED	104	53	21.21	2.16	1.55	3.01	104	53	21.17	2.16	1.55	3.01
VAGINAL DISCHARGE	84	41	18.54	2.26	1.55	3.28	84	41	18.50	2.26	1.55	3.28
ANKYLOSING SPONDYLITIS	25	8	9.41	3.44	1.55	7.64	24	8	8.57	3.30	1.48	7.35
BODY TEMPERATURE ABNORMAL	105	54	21.01	2.14	1.54	2.98	105	53	22.67	2.22	1.60	3.10
BONE DISORDER	32	12	10.18	2.94	1.51	5.71	32	12	10.16	2.94	1.51	5.70
UTERINE SPASM	79	40	16.15	2.18	1.49	3.18	79	40	16.12	2.18	1.49	3.18
HAEMOGLOBIN DECREASED	37	15	10.67	2.72	1.49	4.95	37	15	10.65	2.72	1.49	4.95
WALKING DISABILITY	22	7	8.21	3.46	1.48	8.11	22	7	8.20	3.46	1.48	8.10
BLOOD BILIRUBIN INCREASED	14	3	6.91	5.14	1.48	17.90	14	3	6.90	5.14	1.48	17.88
HASHIMOTO'S DISEASE	57	27	13.06	2.33	1.47	3.68	57	27	13.04	2.33	1.47	3.68
FACIAL SPASM	57	27	13.06	2.33	1.47	3.68	58	27	13.72	2.37	1.50	3.74
ROAD TRAFFIC ACCIDENT	57	27	13.06	2.33	1.47	3.68	57	27	13.04	2.33	1.47	3.68
C-REACTIVE PROTEIN INCREASED	38	16	10.36	2.62	1.46	4.69	37	15	10.65	2.72	1.49	4.95
HANGOVER	58	28	12.83	2.28	1.45	3.58	58	28	12.81	2.28	1.45	3.58
WHITE BLOOD CELL COUNT DECREASED	48	23	11.55	2.40	1.45	3.98	48	21	12.50	2.52	1.51	4.20
NASAL PRURITUS	57	28	12.18	2.24	1.43	3.53	57	28	12.15	2.24	1.43	3.52
PSORIATIC ARTHROPATHY	54	26	11.96	2.29	1.43	3.65	54	25	12.84	2.38	1.48	3.82
MASTITIS	63	32	12.65	2.17	1.42	3.32	63	32	12.62	2.17	1.42	3.32
WRONG PATIENT	32	13	9.08	2.71	1.42	5.17	32	13	9.06	2.71	1.42	5.17
EYE OEDEMA	23	8	7.78	3.17	1.42	7.08	23	7	9.04	3.62	1.55	8.43
OVARIAN CYST	69	36	13.14	2.11	1.41	3.16	69	36	13.12	2.11	1.41	3.16
FRUSTRATION TOLERANCE DECREASED	67	35	12.71	2.11	1.40	3.18	67	35	12.68	2.11	1.40	3.17
SPUTUM DISCOLOURED	68	36	12.53	2.08	1.39	3.12	68	35	13.30	2.14	1.42	3.22
APRAXIA	19	6	7.00	3.49	1.39	8.74	19	6	6.99	3.49	1.39	8.73
PHARYNGITIS STREPTOCOCCAL	52	26	10.65	2.20	1.38	3.53	50	25	10.20	2.20	1.36	3.56
CLAUSTROPHOBIA	17	5	6.64	3.75	1.38	10.16	16	5	5.79	3.52	1.29	9.62
PETIT MAL EPILEPSY	34	9	7.40	2.94	1.37	6.32	34	9	7.38	2.94	1.37	6.32
SLEEP DISORDER DUE TO A GENERAL MEDICAL CONDITION	13	3	5.99	4.78	1.36	16.76	13	3	5.98	4.77	1.36	16.75
INCREASED APPETITE	54	28	10.27	2.13	1.35	3.36	54	28	10.25	2.12	1.35	3.35
HORMONE LEVEL ABNORMAL	55	29	10.09	2.09	1.33	3.28	55	29	10.07	2.09	1.33	3.28
MAST CELL ACTIVATION SYNDROME	30	13	7.63	2.54	1.33	4.88	31	13	8.33	2.63	1.37	5.02

ABNORMAL UTERINE BLEEDING	39	19	8.23	2.26	1.31	3.91	39	19	8.21	2.26	1.31	3.91
HYPOTENSIVE TO STIMULI	23	9	6.64	2.82	1.30	6.09	23	9	6.63	2.81	1.30	6.08
SUBMAXILLARY GLAND ENLARGEMENT	23	9	6.64	2.82	1.30	6.09	23	9	6.63	2.81	1.30	6.08
PLATELET COUNT INCREASED	26	11	6.76	2.61	1.29	5.27	26	10	7.80	2.86	1.38	5.94
DEMYELINATION	16	5	5.80	3.53	1.29	9.63	16	5	5.79	3.52	1.29	9.62
PHARYNGEAL DISORDER	16	5	5.80	3.53	1.29	9.63	16	5	5.79	3.52	1.29	9.62
NAIL DISCOLOURATION	53	29	8.90	2.01	1.28	3.17	53	28	9.64	2.08	1.32	3.30
ATELECTASIS	50	27	8.63	2.04	1.28	3.26	50	27	8.61	2.04	1.28	3.26
THYROIDITIS	44	23	8.09	2.11	1.27	3.49	44	23	8.08	2.11	1.27	3.49
RETINAL VEIN OCCLUSION	33	16	6.91	2.27	1.25	4.13	34	16	7.56	2.34	1.29	4.24
BREAST ENLARGEMENT	43	23	7.49	2.06	1.24	3.42	42	23	6.89	2.01	1.21	3.34
CEREBRAL INFARCTION	12	3	5.09	4.41	1.24	15.63	12	3	5.09	4.41	1.24	15.61
SICK RELATIVE	12	3	5.09	4.41	1.24	15.63	12	3	5.09	4.41	1.24	15.61
ACUTE KIDNEY INJURY	44	24	7.33	2.02	1.23	3.32	44	24	7.32	2.02	1.23	3.32
ACUTE RESPIRATORY FAILURE	17	6	5.39	3.12	1.23	7.92	16	6	4.61	2.94	1.15	7.51
ATTENTION DEFICIT	17	6	5.39	3.12	1.23	7.92	17	7	4.31	2.67	1.11	6.45
HYPERACTIVITY DISORDER	41	22	7.06	2.05	1.22	3.45	39	21	6.61	2.05	1.20	3.48
VIBRATORY SENSE INCREASED	42	23	6.90	2.01	1.21	3.35	42	23	6.89	2.01	1.21	3.34
MENTAL FATIGUE	35	18	6.53	2.14	1.21	3.78	35	18	6.51	2.14	1.21	3.78
UTERINE PAIN												
INCORRECT PRODUCT ADMINISTRATION DURATION	23	10	5.62	2.53	1.21	5.33	23	10	5.61	2.53	1.21	5.32
POST-TRAUMATIC STRESS DISORDER	20	8	5.47	2.76	1.21	6.26	20	8	5.46	2.75	1.21	6.25
POLYURIA	36	19	6.36	2.09	1.20	3.64	36	19	6.34	2.09	1.20	3.64
EPICONDYLITIS	26	12	5.81	2.39	1.20	4.73	27	11	4.73	2.70	1.34	5.45
GINGIVAL DISORDER	15	5	4.98	3.31	1.20	9.10	15	5	4.98	3.30	1.20	9.09
BLADDER DISORDER	33	17	6.09	2.14	1.19	3.84	33	17	6.08	2.14	1.19	3.84
TIC	33	17	6.09	2.14	1.19	3.84	33	17	6.08	2.14	1.19	3.84
PHARYNGEAL ULCERATION	21	9	5.19	2.57	1.18	5.61	20	8	5.46	2.75	1.21	6.25
LABORATORY TEST ABNORMAL	18	7	5.04	2.83	1.18	6.79	18	7	5.04	2.83	1.18	6.78
LIVER DISORDER	31	16	5.66	2.14	1.17	3.90	30	16	5.05	2.07	1.13	3.79
POLYARTHITIS	31	16	5.66	2.14	1.17	3.90	31	16	5.64	2.13	1.17	3.90
BLOOD POTASSIUM INCREASED	13	4	4.59	3.58	1.17	10.99	13	4	4.59	3.58	1.17	10.98
NEUTROPHIL COUNT DECREASED	13	4	4.59	3.58	1.17	10.99	13	4	4.59	3.58	1.17	10.98
VISUAL ACUTY REDUCED	28	14	5.40	2.20	1.16	4.19	28	14	5.39	2.20	1.16	4.18
TONGUE MOVEMENT DISTURBANCE	22	10	4.94	2.42	1.15	5.12	22	10	4.93	2.42	1.15	5.12
BREAST INDURATION	19	8	4.75	2.62	1.15	5.98	19	8	4.74	2.62	1.15	5.98
ENDOMETRIAL THICKENING	19	8	4.75	2.62	1.15	5.98	19	8	4.74	2.62	1.15	5.98
ILLUSION	16	6	4.62	2.94	1.15	7.51	16	6	4.61	2.94	1.15	7.51
TOOTH EXTRACTION	16	6	4.62	2.94	1.15	7.51	16	6	4.61	2.94	1.15	7.51
ALANINE AMINOTRANSFERASE INCREASED	33	18	5.34	2.02	1.14	3.59	33	18	5.33	2.02	1.14	3.59
NEOPLASM	33	18	5.34	2.02	1.14	3.59	33	17	6.08	2.14	1.19	3.84
TOOTH DISORDER	33	18	5.34	2.02	1.14	3.59	33	17	6.08	2.14	1.19	3.84
GLUTEN SENSITIVITY	11	3	4.23	4.04	1.13	14.49	11	3	4.22	4.04	1.13	14.48
LABILE BLOOD PRESSURE	11	3	4.23	4.04	1.13	14.49	11	3	4.22	4.04	1.13	14.48
SPECTUM INCREASED	11	3	4.23	4.04	1.13	14.49	11	3	4.22	4.04	1.13	14.48
PAROTID GLAND ENLARGEMENT	23	11	4.72	2.30	1.12	4.73	23	11	4.71	2.30	1.12	4.72
INTRACRANIAL PRESSURE INCREASED	20	9	4.50	2.45	1.12	5.38	20	9	4.49	2.45	1.11	5.38

ANAL HAEMORRHAGE	14	5	4.20	3.09	1.11	8.57	14	5	4.19	3.08	1.11	8.56
EMANCIPATION/ANXIETY	14	5	4.20	3.09	1.11	8.57	14	5	4.19	3.08	1.11	8.56
RELATED REACTION	14	5	4.20	3.09	1.11	8.57	14	5	4.19	3.08	1.11	8.56
PATIENT ISOLATION	21	10	4.28	2.31	1.09	4.91	21	10	4.27	2.31	1.09	4.91
TRIDOCYCLITIS	21	10	4.28	2.31	1.09	4.91	21	10	4.27	2.31	1.09	4.91
OVERSENSING	21	10	4.28	2.31	1.09	4.91	21	10	4.27	2.31	1.09	4.91
THYROID PAIN	21	10	4.28	2.31	1.09	4.91	21	10	4.27	2.31	1.09	4.91
MUSCLE INJURY	26	14	4.30	2.05	1.07	3.92	26	13	4.95	2.20	1.13	4.59
RESPIRATORY DISORDER	120	66	20.75	2.00	1.48	2.71	118	66	19.54	1.97	1.46	2.66
VASCULAR PAIN	60	33	10.04	2.00	1.31	3.06	59	33	9.44	1.97	1.29	3.02
THERAPEUTIC PRODUCT	11	3	4.22	4.04	1.13	14.49	10	3	3.39	3.67	1.01	13.34
EFFECT DECREASED	31	17	4.91	2.01	1.11	3.63	30	17	4.34	1.94	1.07	3.52
SIODREN'S SYNDROME	50	1	50.09	55.11	7.61	398.92	50	1	50.05	55.07	7.61	398.64
BODY HEIGHT DECREASED	17	2	11.75	9.37	2.16	40.55	17	2	11.74	9.36	2.16	40.52
SALIVARY GLAND PAIN	15	2	9.70	8.27	1.89	36.15	15	2	9.69	8.26	1.89	36.12
PHARYNGEAL INFLAMMATION	12	1	8.72	13.23	1.72	101.71	12	1	8.71	13.22	1.72	101.64
LYMPHOCYTE COUNT	12	2	6.71	6.61	1.48	29.55	12	2	6.70	6.61	1.48	29.53
DECREASED	10	1	6.64	11.02	1.41	86.10	10	1	6.63	11.01	1.41	86.04
VENOUS THROMBOSIS	11	2	5.75	6.06	1.34	27.35	11	2	5.74	6.06	1.34	27.33
HYPOAESTHESIA TIBETH	9	1	5.62	9.92	1.26	78.29	9	1	5.61	9.91	1.26	78.24
GESTATIONAL DIABETES	9	1	5.62	9.92	1.26	78.29	9	1	5.61	9.91	1.26	78.24
INFLAMMATORY MARKER	9	1	5.62	9.92	1.26	78.29	9	1	5.61	9.91	1.26	78.24
INCREASED	9	1	5.62	9.92	1.26	78.29	9	1	5.61	9.91	1.26	78.24
POTENTIATING DRUG	9	1	5.62	9.92	1.26	78.29	9	1	5.61	9.91	1.26	78.24
INTERACTION	9	1	5.62	9.92	1.26	78.29	9	1	5.61	9.91	1.26	78.24
THERAPEUTIC RESPONSE	9	1	5.62	9.92	1.26	78.29	9	1	5.61	9.91	1.26	78.24
SHORTENED	9	1	5.62	9.92	1.26	78.29	9	1	5.61	9.91	1.26	78.24
WOUND DRAINAGE	9	1	5.62	9.92	1.26	78.29	9	1	5.61	9.91	1.26	78.24
BRAIN INJURY	10	2	4.80	5.51	1.21	25.15	10	2	4.80	5.51	1.21	25.13
BRAIN NEOPLASM	10	2	4.80	5.51	1.21	25.15	10	2	4.80	5.51	1.21	25.13
CLONUS	10	2	4.80	5.51	1.21	25.15	10	2	4.80	5.51	1.21	25.13
CYST RUPTURE	10	2	4.80	5.51	1.21	25.15	10	2	4.80	5.51	1.21	25.13
HYPOMAGNESAEMIA	10	2	4.80	5.51	1.21	25.15	10	2	4.80	5.51	1.21	25.13
ALOPECIA UNIVERSALIS	8	1	4.63	8.82	1.10	70.50	8	1	4.61	8.81	1.10	70.45
CEREBROSPINAL FLUID	8	1	4.63	8.82	1.10	70.50	8	1	4.61	8.81	1.10	70.45
LEAKAGE	8	1	4.63	8.82	1.10	70.50	8	1	4.61	8.81	1.10	70.45
CHRONIC PIGMENTED PURPURA	8	1	4.62	8.82	1.10	70.50	8	1	4.61	8.81	1.10	70.45
FISTULACTIAN TUBE	8	1	4.62	8.82	1.10	70.50	8	1	4.61	8.81	1.10	70.45
OBSTRUCTION	8	1	4.62	8.82	1.10	70.50	8	1	4.61	8.81	1.10	70.45
VENTRICULAR ARRHYTHMIA	8	1	4.63	8.82	1.10	70.50	8	1	4.61	8.81	1.10	70.45
SCIATIC NERVE INJURY	8	1	4.63	8.82	1.10	70.50	8	1	4.61	8.81	1.10	70.45
HEAVY MENSTRUAL BLEEDING	2614	1442	465.93	2.00	1.87	2.13	2610	1432	470.21	2.01	1.88	2.14
SOMNAMBULISM	18	10	2.50	1.98	0.92	4.30	18	8	4.05	2.48	1.08	5.70

PREFERRED Medical Dictionary for Regulatory Activities (MedDRA) Terms (VAERS-1 Box 7, VAERS 2.0 Box 18)

For Current Week and Past Week Comparison

Following **ALL 12/14/2020-04/22/2022 COVID19 MODERNA Ages 18+ Vaccines**

Compared to **ALL 12/14/2020-04/22/2022 COVID19 PFIZER Ages 18+ Vaccines**

AGES 18+ YEARS, Initial domestic reports only, VAERS reports as of 04/22/2022

Vaccination, Received, and Completed Date: 12/14 - 04/22 (Current Week) and 12/14 - 04/15 (Past Week)

N>=3 (Current Week), PRR>=2.00 (Ratio of Proportions), Chi-Square>=4.00

MedDRA PTs sorting based on lower confidence limit and MODERNA adverse event count from 12/14/2020-04/22/2022

AGES 18+ YEARS excludes missing ages

MedDRA Codes ALL Reports (18+)	12/14/2020- 04/22/2022 MODERNA N=324518	12/14/2020- 04/22/2022 PFIZER N=303997	12/14-04/22 Chi-Square	12/14-04/22 PRR	12/14-04/22 LCL	12/14-04/22 UCL	12/14/2020- 04/15/2022 MODERNA N=323433	12/14/2020- 04/15/2022 PFIZER N=303122	12/14-04/15 Chi-Square	12/14-04/15 PRR	12/14-04/15 LCL	12/14-04/15 UCL
PRODUCT DOSE OMISSION												
ISSUE	1627	71	1329.32	21.47	16.93	27.22	1627	71	1330.01	21.48	16.93	27.24
MECHANICAL URTICARIA	760	59	554.77	12.07	9.26	15.73	755	56	557.65	12.64	9.63	16.58
ACCIDENTAL OVERDOSE	285	21	209.52	12.71	8.16	19.80	277	20	204.69	12.98	8.25	20.43
VACCINATION SITE												
INDURATION	1083	103	747.67	9.85	8.05	12.05	1083	103	748.10	9.85	8.05	12.06
INTENTIONAL PRODUCT USE												
ISSUE	132	9	97.87	13.74	6.99	26.99	132	9	97.92	13.75	7.00	27.00
INJECTION SITE RASH	10224	1396	6263.67	6.86	6.49	7.25	10232	1390	6287.59	6.90	6.52	7.29
INJECTION SITE PRURITUS	18112	2592	11015.40	6.55	6.28	6.82	18120	2587	11041.19	6.56	6.30	6.84
INJECTION SITE INDURATION	5062	736	2980.62	6.44	5.96	6.96	5062	731	2992.62	6.49	6.01	7.01
INJECTION SITE WARMTH	13072	2102	7415.94	5.83	5.56	6.10	13092	2093	7456.77	5.86	5.60	6.14
DEVICE CONNECTION ISSUE	301	42	177.87	6.71	4.86	9.27	301	42	177.98	6.72	4.86	9.28
INJECTION SITE ERYTHEMA	25257	4777	13308.00	4.95	4.80	5.11	25277	4759	13370.46	4.98	4.83	5.13
TYPE IV HYPERSENSITIVITY												
REACTION	117	13	75.12	8.43	4.75	14.95	117	13	75.16	8.43	4.76	14.96
INTENTIONAL DOSE OMISSION	85	9	55.11	8.85	4.45	17.59	84	9	54.25	8.75	4.40	17.39
PRODUCT LABEL CONFUSION	44	3	31.52	13.74	4.27	44.25	44	3	31.53	13.75	4.27	44.27
VACCINATION SITE PRURITUS	3265	677	1544.35	4.52	4.16	4.91	3264	676	1546.38	4.53	4.17	4.92
VACCINATION SITE WARMTH	2713	559	1287.66	4.55	4.15	4.98	2713	553	1298.80	4.60	4.20	5.04
VACCINATION SITE RASH	2070	435	966.70	4.46	4.02	4.94	2068	434	967.45	4.47	4.03	4.95
VACCINATION SITE REACTION	1049	213	500.83	4.61	3.98	5.35	1047	210	504.66	4.67	4.03	5.42
INJECTION SITE REACTION	4034	886	1828.93	4.27	3.97	4.59	4035	882	1837.71	4.29	3.99	4.61
INJECTION SITE URTICARIA	1272	268	591.48	4.45	3.90	5.07	1272	265	596.93	4.50	3.94	5.13
INJECTION SITE												
HYPERSENSITIVITY	151	24	82.79	5.89	3.83	9.07	151	24	82.85	5.90	3.83	9.07
INJECTION SITE												
INFLAMMATION	871	183	405.16	4.46	3.80	5.23	873	182	408.77	4.50	3.83	5.27
INJECTION SITE SWELLING	19603	4902	8213.04	3.75	3.63	3.86	19606	4891	8240.16	3.76	3.64	3.87
VACCINATION SITE												
LYMPHADENOPATHY	155	27	80.63	5.38	3.57	8.09	155	26	82.52	5.59	3.69	8.46
INJECTION SITE PAPULE	53	6	32.96	8.27	3.56	19.25	53	6	32.98	8.28	3.56	19.26
INDURATION	1711	408	720.43	3.93	3.53	4.38	1712	408	721.80	3.93	3.53	4.38
EXPIRED PRODUCT												
ADMINISTERED	11817	3060	4714.01	3.62	3.48	3.76	11532	3041	4520.80	3.55	3.42	3.70
INJECTION SITE IRRITATION	261	53	123.47	4.61	3.43	6.20	260	53	122.74	4.60	3.42	6.18
VACCINATION SITE ERYTHEMA	4874	1266	1910.66	3.61	3.39	3.84	4869	1261	1915.74	3.62	3.40	3.85
INJECTION SITE CELLULITIS	331	71	150.64	4.37	3.38	5.64	329	69	152.43	4.47	3.45	5.79
PRODUCT ADMINISTRATION												
INTERRUPTED	31	3	19.74	9.68	2.96	31.66	31	3	19.75	9.68	2.96	31.68
INJECTION SITE MASS	2306	691	771.50	3.13	2.87	3.40	2307	688	776.87	3.14	2.89	3.42
LOCAL REACTION	233	59	91.65	3.70	2.78	4.92	233	57	94.71	3.83	2.87	5.12

SKIN WARM	6807	2195	2102.67	2.91	2.77	3.95	6808	2190	2111.68	2.91	2.78	3.06
VACCINATION SITE URTICARIA	252	67	94.61	3.52	2.69	4.61	252	67	94.69	3.52	2.69	4.61
POOR QUALITY PRODUCT ADMINISTERED	712	214	235.88	3.12	2.68	3.63	693	211	226.26	3.08	2.64	3.59
INJECTION SITE NODULE	898	275	291.31	3.06	2.67	3.50	898	275	291.58	3.06	2.67	3.50
VACCINATION COMPLICATION	2660	884	782.11	2.82	2.61	3.04	2659	886	779.82	2.81	2.61	3.03
SKIN INDURATION	162	42	61.95	3.61	2.57	5.07	162	41	63.46	3.70	2.63	5.22
SKIN REACTION	551	170	176.62	3.04	2.56	3.61	552	170	177.50	3.04	2.56	3.61
MATERNAL EXPOSURE DURING PREGNANCY	720	232	218.91	2.91	2.51	3.37	720	229	222.80	2.95	2.54	3.42
VACCINATION SITE DISCOLOURATION	258	75	88.08	3.22	2.49	4.17	258	74	89.50	3.27	2.52	4.23
INJECTION SITE OEDEMA	175	48	63.29	3.42	2.48	4.70	175	48	63.35	3.42	2.48	4.70
VACCINATION SITE MOVEMENT IMPAIRMENT	268	82	86.22	3.06	2.39	3.92	266	81	86.14	3.08	2.40	3.95
INJECTION SITE INDENTATION	99	25	38.39	3.71	2.39	5.75	100	25	39.19	3.75	2.42	5.81
VACCINATION SITE SWELLING	3754	1428	905.28	2.46	2.32	2.62	3749	1423	908.31	2.47	2.32	2.62
INJECTION SITE DISCOLOURATION	473	162	132.05	2.74	2.29	3.27	472	160	133.82	2.76	2.31	3.31
VACCINATION SITE DISCHARGE	41	8	18.88	4.80	2.25	10.24	41	8	18.90	4.80	2.25	10.25
CHRONIC SPONTANEOUS URTICARIA	116	33	39.98	3.29	2.24	4.85	116	33	40.02	3.29	2.24	4.85
CELLULITIS	1186	448	287.08	2.48	2.22	2.76	1180	445	286.71	2.49	2.23	2.77
POST-ACUTE COVID-19 SYNDROME	230	75	68.13	2.87	2.21	3.73	227	74	67.32	2.87	2.21	3.74
RASH ERYTHEMATOUS	7311	3044	1516.53	2.25	2.16	2.35	7304	3033	1524.60	2.26	2.16	2.35
PRODUCT AVAILABILITY ISSUE	26	4	13.38	6.09	2.13	17.45	26	4	13.38	6.09	2.13	17.45
INJECTION SITE STREAKING	48	11	19.70	4.09	2.12	7.87	47	11	18.93	4.00	2.08	7.72
EXPOSURE VIA SKIN CONTACT	119	38	35.75	2.93	2.04	4.23	119	38	35.79	2.93	2.04	4.23
ERYTHEMA	15843	7187	2818.21	2.07	2.01	2.12	15831	7161	2837.72	2.07	2.02	2.13
EXPOSURE VIA BREAST MILK	54	14	19.92	3.61	2.01	6.50	54	14	19.93	3.61	2.01	6.51
INJECTION SITE INFECTION	106	35	30.37	2.84	1.94	4.16	106	35	30.40	2.84	1.94	4.16
INJECTION SITE ABSCESS	81	25	25.09	3.04	1.94	4.75	81	25	25.11	3.04	1.94	4.75
SKIN SWELLING	486	200	100.74	2.28	1.93	2.68	488	200	102.06	2.29	1.94	2.70
VACCINATION SITE CELLULITIS	45	13	14.62	3.24	1.75	6.01	45	13	14.64	3.24	1.75	6.01
ERYTHEMA MULTIFORME	130	51	28.75	2.39	1.73	3.30	130	51	28.78	2.39	1.73	3.30
ANTIBODY TEST NEGATIVE	24	5	10.04	4.50	1.72	11.78	24	5	10.05	4.50	1.72	11.79
VACCINATION SITE INFLAMMATION	160	67	31.57	2.24	1.68	2.98	160	66	32.52	2.27	1.71	3.03
SKIN INFECTION	66	23	17.19	2.69	1.67	4.32	64	24	14.87	2.50	1.56	4.00
URTICARIA CHRONIC	122	53	22.20	2.16	1.56	2.98	117	52	20.29	2.11	1.52	2.92
INJECTION SITE MACULE	22	5	8.47	4.12	1.56	10.88	22	5	8.48	4.12	1.56	10.89
INJECTION SITE PUSTULE	37	12	10.25	2.89	1.51	5.54	37	12	10.26	2.89	1.51	5.54
INJECTION SITE EXTRAVASATION	91	39	16.84	2.19	1.50	3.18	91	39	16.86	2.19	1.50	3.18
INJECTION SITE LYMPHADENOPATHY	84	38	13.81	2.07	1.41	3.04	84	37	14.65	2.13	1.45	3.13
TOOTH LOSS	22	6	7.09	3.43	1.39	8.47	22	5	8.48	4.12	1.56	10.89
INJECTION SITE SCAR	38	14	8.74	2.54	1.38	4.69	38	14	8.75	2.54	1.38	4.69
INJECTION SITE SCAB	57	25	9.79	2.14	1.33	3.42	57	25	9.81	2.14	1.34	3.42
VACCINATION SITE SCAR	25	8	6.76	2.93	1.32	6.49	25	8	6.76	2.93	1.32	6.49
MULTIPLE USE OF SINGLE-USE PRODUCT	14	3	5.25	4.37	1.26	15.21	14	3	5.26	4.37	1.26	15.22
DENTAL DISCOMFORT	39	17	6.57	2.15	1.22	3.80	39	16	7.44	2.28	1.28	4.09
MYOSCLEROSIS	37	16	6.30	2.17	1.21	3.89	37	15	7.18	2.31	1.27	4.21
UJMB IMMOBILISATION	32	13	6.08	2.31	1.21	4.39	32	13	6.09	2.31	1.21	4.40

FEELING OF RELAXATION	26	10	5.31	2.44	1.17	5.05	26	10	5.32	2.44	1.18	5.05
PRODUCT COLOUR ISSUE	13	3	4.50	4.06	1.16	14.24	13	3	4.50	4.06	1.16	14.25
GINGIVITIS	22	8	4.82	2.58	1.15	5.79	21	8	4.22	2.46	1.09	5.55
LEFT VENTRICULAR ENLARGEMENT	18	6	4.35	2.81	1.12	7.08	18	6	4.36	2.81	1.12	7.08
ACCIDENTAL UNDERDOSE	204	2	183.47	95.55	23.74	384.65	201	2	180.75	94.19	23.40	379.20
VACCINATION SITE DYSAESTHESIA	20	1	14.29	18.74	2.51	139.60	20	1	14.30	18.74	2.52	139.66
PRODUCT CONTAMINATION PHYSICAL	19	1	13.38	17.80	2.38	132.95	19	1	13.38	17.81	2.38	133.01
VACCINATION SITE ANAESTHESIA	19	1	13.38	17.80	2.38	132.95	19	1	13.38	17.81	2.38	133.01
VACCINATION SITE HYPERSENSITIVITY	16	2	8.57	7.49	1.72	32.59	16	2	8.57	7.50	1.72	32.61
PRODUCT EXPIRATION DATE ISSUE	13	2	6.04	6.09	1.37	26.98	13	2	6.04	6.09	1.37	26.99
VACCINATION SITE STREAKING	11	2	4.42	5.15	1.14	23.24	11	2	4.42	5.15	1.14	23.25
VACCINATION SITE NODULE	85	40	12.76	1.99	1.37	2.90	84	39	13.03	2.02	1.38	2.95
INJECTION RELATED REACTION	20	9	2.83	2.08	0.95	4.57	20	7	4.59	2.68	1.13	6.33

PREFERRED Medical Dictionary for Regulatory Activities (MedDRA) Terms (VAERS-1 Box 7, VAERS 2.0 Box 18)

For Current Week and Past Week Comparison

Following **ALL 12/14/2020-04/22/2022 COVID19 MODERNA Ages 18+ Vaccines**Compared to **ALL 12/14/2020-04/22/2022 COVID19 PFIZER Ages 18+ Vaccines****SERIOUS AGES 18+ YEARS**, Initial domestic reports only, VAERS reports as of 04/22/2022

Vaccination, Received, and Completed Date: 12/14 - 04/22 (Current Week) and 12/14 - 04/15 (Past Week)

N $\geq$ 3 (Current Week), PRR $\geq$ 2.00 (Ratio of Proportions), Chi-Square $\geq$ 4.00

MedDRA PTs sorting based on lower confidence limit and MODERNA adverse event count from 12/14/2020-04/22/2022

SERIOUS AGES 18+ YEARS excludes missing ages

MedDRA Codes ALL Reports (SERIOUS 18+)	12/14/2020- 04/22/2022 MODERNA N=30309	12/14/2020- 04/22/2022 PFIZER N=37058	12/14-04/22 Chi-Square	12/14-04/22 PRR	12/14-04/22 LCL	12/14-04/22 UCL	12/14/2020- 04/15/2022 MODERNA N=30088	12/14/2020- 04/15/2022 PFIZER N=36782	12/14-04/15 Chi-Square	12/14-04/15 PRR	12/14-04/15 LCL	12/14-04/15 UCL
PRODUCT DOSE OMISSION	127	18	104.81	8.63	5.27	14.13	127	18	104.79	8.63	5.27	14.13
MECHANICAL URTICARIA	20	3	14.72	8.15	2.42	27.43	20	3	14.72	8.15	2.42	27.42
INJECTION SITE ERYTHEMA	138	55	53.90	3.07	2.25	4.19	136	54	53.34	3.08	2.25	4.22
VACCINATION SITE ERYTHEMA	35	12	15.34	3.57	1.85	6.87	35	12	15.34	3.57	1.85	6.87
INJECTION SITE PRURITUS	66	29	22.06	2.78	1.80	4.31	63	28	20.66	2.75	1.76	4.29
INJECTION SITE SWELLING	146	77	37.09	2.32	1.76	3.05	143	75	36.68	2.33	1.76	3.08
INJECTION SITE WARMTH	57	26	17.89	2.68	1.69	4.26	53	26	14.72	2.49	1.56	3.98
INCOMPLETE COURSE OF VACCINATION	99	56	21.62	2.16	1.56	3.00	99	56	21.61	2.16	1.56	3.00
INJECTION SITE REACTION	46	22	13.22	2.56	1.54	4.25	46	22	13.21	2.56	1.54	4.25
DRUG REACTION WITH EOSINOPHILIA AND SYSTEMIC SYMPTOMS	17	5	8.01	4.16	1.53	11.27	17	5	8.01	4.16	1.53	11.26
OPTIC ISCHAEMIC NEUROPATHY	20	7	8.09	3.49	1.48	8.26	20	7	8.09	3.49	1.48	8.26
GRANULOMA	14	4	6.55	4.28	1.41	13.00	14	4	6.55	4.28	1.41	13.00
VACCINATION SITE RASH	14	4	6.55	4.28	1.41	13.00	14	4	6.55	4.28	1.41	13.00
VACCINATION SITE REACTION	14	4	6.55	4.28	1.41	13.00	14	4	6.55	4.28	1.41	13.00
INJECTION SITE INDURATION	27	12	8.31	2.75	1.39	5.43	26	12	7.51	2.65	1.34	5.25
VACCINATION SITE WARMTH	17	6	6.65	3.46	1.37	8.79	17	6	6.65	3.46	1.37	8.78
SUDDEN CARDIAC DEATH	42	24	8.54	2.14	1.30	3.53	42	23	9.34	2.23	1.34	3.71
CHOLECYSTITIS INFECTIVE	16	6	5.77	3.26	1.28	8.33	16	6	5.76	3.26	1.28	8.33
RASH PAPULAR	40	23	7.99	2.13	1.27	3.55	40	23	7.99	2.13	1.27	3.55
ECTOPIC PREGNANCY	11	3	5.10	4.48	1.25	16.07	10	3	4.14	4.07	1.12	14.81
VENA CAVA THROMBOSIS	11	3	5.10	4.48	1.25	16.07	12	3	6.08	4.89	1.38	17.33
CARDIAC DISCOMFORT	21	10	5.60	2.57	1.21	5.45	21	10	5.60	2.57	1.21	5.45
IMPAIRED HEALING	25	13	5.83	2.35	1.20	4.60	24	13	5.13	2.26	1.15	4.43
FACET JOINT SYNDROME	15	6	4.91	3.06	1.19	7.88	15	6	4.91	3.06	1.19	7.88
DISSOCIATION	12	4	4.67	3.67	1.18	11.37	12	4	4.67	3.67	1.18	11.37
LEFT VENTRICULAR ENLARGEMENT	12	4	4.67	3.67	1.18	11.37	12	4	4.67	3.67	1.18	11.37
B-CELL LYMPHOMA	13	5	4.35	3.18	1.13	8.92	13	5	4.35	3.18	1.13	8.91
NERVE BLOCK	10	3	4.14	4.08	1.12	14.81	10	3	4.14	4.07	1.12	14.81
MYOCARDIAL FIBROSIS	28	17	4.73	2.01	1.10	3.68	28	17	4.73	2.01	1.10	3.68
TOBACCO USER	28	17	4.73	2.01	1.10	3.68	27	16	4.81	2.06	1.11	3.83
RIGHT VENTRICULAR FAILURE	25	15	4.28	2.04	1.07	3.86	25	15	4.27	2.04	1.07	3.86
SLEEP DEFICIT	13	2	8.91	7.95	1.79	35.21	13	2	8.91	7.95	1.79	35.21
VACCINATION SITE INDURATION	12	2	7.81	7.34	1.64	32.78	12	2	7.81	7.33	1.64	32.77
INTENTIONAL DOSE OMISSION	11	2	6.73	6.72	1.49	30.34	11	2	6.72	6.72	1.49	30.33
CHRONIC SPONTANEOUS URTICARIA	10	2	5.66	6.11	1.34	27.90	10	2	5.66	6.11	1.34	27.89

CONNECTIVE TISSUE DISORDER	10	2	5.66	6.11	1.34	27.90	9	2	4.63	5.50	1.19	25.46
MEDICAL DEVICE												
IMPLANTATION	10	2	5.66	6.11	1.34	27.90	10	2	5.66	6.11	1.34	27.89
PULMONARY HILUM MASS	10	2	5.66	6.11	1.34	27.90	10	2	5.66	6.11	1.34	27.89
HYPERAMMONAEMIA	8	1	5.35	9.78	1.22	78.20	8	1	5.35	9.78	1.22	78.19
SCHIZOPHRENIA	9	2	4.63	5.50	1.19	25.46	9	2	4.63	5.50	1.19	25.46
EX TOBACCO USER	9	2	4.63	5.50	1.19	25.46	8	2	3.64	4.89	1.04	23.03
SKIN ODOUR ABNORMAL	5	1	2.18	6.11	0.71	52.32	5	0	.	.	.	.

PREFERRED Medical Dictionary for Regulatory Activities (MedDRA) Terms (VAERS-1 Box 7, VAERS 2.0 Box 18)

For Current Week and Past Week Comparison

Following **ALL 12/14/2020-04/22/2022 COVID19 MODERNA Ages 18+ Vaccines**

Compared to **ALL 12/14/2020-04/22/2022 COVID19 PFIZER Ages 18+ Vaccines**

NON-SERIOUS AGES 18+ YEARS, Initial domestic reports only, VAERS reports as of 04/22/2022

Vaccination, Received, and Completed Date: 12/14 - 04/22 (Current Week) and 12/14 - 04/15 (Past Week)

N>=3 (Current Week), PRR>=2.00 (Ratio of Proportions), Chi-Square>=4.00

MedDRA PTs sorting based on lower confidence limit and MODERNA adverse event count from 12/14/2020-04/22/2022

NON-SERIOUS AGES 18+ YEARS excludes missing ages

MedDRA Codes ALL Reports (NON-SERIOUS 18+)	12/14/2020- 04/22/2022 MODERNA N=294209	12/14/2020- 04/22/2022 PFIZER N=266939	12/14-04/22 Chi-Square	12/14-04/22 PRR	12/14-04/22 LCL	12/14-04/22 UCL	12/14/2020- 04/15/2022 MODERNA N=293345	12/14/2020- 04/15/2022 PFIZER N=266340	12/14-04/15 Chi-Square	12/14-04/15 PRR	12/14-04/15 LCL	12/14-04/15 UCL
PRODUCT DOSE OMISSION												
ISSUE	1500	53	1215.73	25.68	19.53	33.77	1500	53	1216.65	25.70	19.54	33.79
ACCIDENTAL OVERDOSE	278	13	215.15	19.40	11.13	33.84	270	12	210.67	20.43	11.46	36.42
MECHANICAL URTICARIA	740	56	523.52	11.99	9.14	15.73	735	53	526.61	12.59	9.53	16.64
VACCINATION SITE INDURATION	1071	101	712.92	9.62	7.85	11.80	1071	101	713.53	9.63	7.85	11.81
INJECTION SITE RASH	10173	1361	6039.84	6.78	6.41	7.17	10182	1355	6066.06	6.82	6.45	7.22
INTENTIONAL PRODUCT USE ISSUE	124	9	87.17	12.50	6.35	24.59	124	9	87.25	12.51	6.36	24.61
INJECTION SITE PRURITUS	18046	2563	10587.31	6.39	6.13	6.66	18057	2559	10616.45	6.41	6.15	6.68
INJECTION SITE INDURATION	5035	724	2856.26	6.31	5.84	6.82	5036	719	2869.84	6.36	5.88	6.88
INJECTION SITE WARMTH	13015	2076	7107.92	5.69	5.43	5.96	13039	2067	7153.62	5.73	5.47	6.00
TYPE IV HYPERSENSITIVITY REACTION	116	11	75.55	9.57	5.16	17.76	116	11	75.62	9.57	5.16	17.77
DEVICE CONNECTION ISSUE	300	41	171.44	6.64	4.79	9.20	300	41	171.60	6.64	4.79	9.21
INJECTION SITE ERYTHEMA	25119	4722	12734.22	4.83	4.68	4.98	25141	4705	12799.73	4.85	4.70	5.00
INTENTIONAL DOSE OMISSION	74	7	47.67	9.59	4.42	20.82	73	7	46.84	9.47	4.56	20.56
PRODUCT LABEL CONFUSION	44	3	30.34	13.31	4.13	42.85	44	3	30.37	13.32	4.13	42.88
VACCINATION SITE PRURITUS	3254	672	1468.92	4.39	4.04	4.77	3253	671	1471.43	4.40	4.05	4.78
VACCINATION SITE WARMTH	2696	553	1221.60	4.42	4.04	4.85	2696	547	1232.99	4.47	4.08	4.91
VACCINATION SITE RASH	2056	431	914.70	4.33	3.90	4.80	2054	430	915.79	4.34	3.91	4.81
INJECTION SITE URTICARIA	1259	356	571.79	4.46	3.90	5.10	1260	353	578.24	4.52	3.95	5.17
INJECTION SITE REACTION	3988	864	1737.14	4.19	3.89	4.51	3989	860	1746.41	4.21	3.91	4.53
VACCINATION SITE REACTION	1035	209	472.04	4.49	3.87	5.21	1033	206	476.00	4.55	3.92	5.29
INJECTION SITE HYPERSENSITIVITY	149	23	79.31	5.88	3.79	9.12	149	23	79.39	5.88	3.79	9.12
INJECTION SITE INFLAMMATION	864	180	384.53	4.36	3.71	5.11	867	179	388.98	4.40	3.74	5.16
INDURATION	1683	383	699.59	3.99	3.57	4.45	1684	383	701.19	3.99	3.57	4.46
INJECTION SITE SWELLING	19457	4825	7806.59	3.66	3.55	3.77	19463	4816	7835.54	3.67	3.56	3.79
INJECTION SITE PAPULE	53	6	31.61	8.01	3.45	18.64	53	6	31.64	8.02	3.45	18.66
VACCINATION SITE LYMPHADENOPATHY	153	27	75.28	5.14	3.42	7.74	153	26	77.15	5.34	3.53	8.10
VACCINATION COMPLICATION	2204	538	861.91	3.72	3.38	4.08	2204	539	861.47	3.71	3.38	4.08
EXPIRED PRODUCT ADMINISTERED	11810	3058	4463.76	3.50	3.37	3.64	11525	3039	4279.53	3.44	3.31	3.58
INJECTION SITE IRRITATION	260	52	118.30	4.54	3.37	6.11	259	52	117.63	4.52	3.36	6.09
INJECTION SITE CELLULITIS	325	68	143.24	4.34	3.34	5.63	323	67	143.46	4.38	3.36	5.69
VACCINATION SITE ERYTHEMA	4839	1254	1797.94	3.50	3.29	3.72	4834	1249	1803.69	3.51	3.30	3.74
CELLULITIS	986	278	331.25	3.22	2.82	3.68	985	277	332.31	3.23	2.83	3.69
INJECTION SITE MASS	2285	678	726.93	3.06	2.81	3.33	2286	675	732.51	3.07	2.82	3.35

SKIN WARM	6663	2079	2013.90	2.91	2.77	3.95	6665	2074	2024.47	2.92	2.78	3.06
PRODUCT ADMINISTRATION INTERRUPTED	30	3	18.08	9.07	2.77	29.73	30	3	18.10	9.08	2.77	29.75
MATERNAL EXPOSURE DURING PREGNANCY	707	202	233.54	3.18	2.72	3.71	707	200	236.50	3.21	2.74	3.75
LOCAL REACTION	229	58	85.10	3.58	2.69	4.78	229	56	88.12	3.71	2.77	4.97
POST-ACUTE COVID-19 SYNDROME	210	53	78.21	3.60	2.66	4.86	208	53	76.83	3.56	2.64	4.82
VACCINATION SITE URTICARIA	249	65	89.87	3.48	2.65	4.57	249	65	89.98	3.48	2.65	4.57
SKIN INDURATION	161	39	62.09	3.75	2.64	5.31	161	38	63.65	3.85	2.70	5.48
POOR QUALITY PRODUCT ADMINISTERED	712	212	224.06	3.05	2.61	3.55	693	209	214.97	3.01	2.58	3.51
INJECTION SITE NODULE	888	270	272.72	2.98	2.60	3.42	889	270	273.79	2.99	2.61	3.43
INJECTION SITE INDENTATION	95	21	39.22	4.10	2.56	6.58	97	21	40.81	4.19	2.62	6.72
SKIN REACTION	538	163	165.44	2.99	2.51	3.57	540	162	168.32	3.03	2.54	3.61
INJECTION SITE OEDEMA	171	45	60.87	3.45	2.48	4.79	171	45	60.94	3.45	2.48	4.79
VACCINATION SITE MOVEMENT IMPAIRMENT	264	76	85.73	3.15	2.44	4.07	262	75	85.75	3.17	2.45	4.10
VACCINATION SITE DISCOLOURATION	257	74	83.41	3.15	2.43	4.08	257	73	84.84	3.20	2.46	4.15
VACCINATION SITE SWELLING	3723	1405	843.49	2.40	2.26	2.56	3718	1400	846.96	2.41	2.27	2.56
INJECTION SITE DISCOLOURATION	471	158	126.36	2.70	2.26	3.24	470	156	128.19	2.74	2.28	3.28
VACCINATION SITE DISCHARGE	41	8	17.95	4.65	2.18	9.92	41	8	17.97	4.65	2.18	9.93
RASH ERYTHEMATOUS	7175	2928	1424.60	2.22	2.13	2.32	7170	2918	1433.72	2.23	2.14	2.33
EXPOSURE VIA BREAST MILK	52	12	20.18	3.93	2.10	7.36	52	12	20.20	3.93	2.10	7.37
PRODUCT AVAILABILITY ISSUE	23	5	12.13	6.96	2.09	23.17	23	5	12.14	6.96	2.09	23.18
CHRONIC SPONTANEOUS URTICARIA	106	31	33.19	3.10	2.08	4.63	106	31	33.23	3.10	2.08	4.63
ERYTHEMA	15404	6736	2716.05	2.07	2.02	2.13	15393	6716	2732.93	2.08	2.02	2.14
INJECTION SITE STREAKING	47	11	17.90	3.88	2.01	7.47	46	11	17.17	3.80	1.97	7.33
ERYTHEMA MULTIFORME	125	40	35.08	2.84	1.99	4.05	125	40	35.13	2.84	1.99	4.05
INJECTION SITE INFECTION	104	32	30.57	2.95	1.98	4.38	104	32	30.61	2.95	1.99	4.39
EXPOSURE VIA SKIN CONTACT	118	38	32.78	2.82	1.95	4.06	118	38	32.83	2.82	1.96	4.06
SKIN SWELLING	475	188	97.49	2.29	1.94	2.71	477	187	99.79	2.32	1.96	2.74
INJECTION SITE ABSCESS	80	24	24.05	3.02	1.92	4.77	80	24	24.08	3.03	1.92	4.78
SKIN INFECTION	59	18	17.12	2.97	1.75	5.04	58	19	15.30	2.77	1.65	4.65
URTICARIA CHRONIC	115	43	25.44	2.43	1.71	3.44	110	42	23.48	2.38	1.67	3.39
ANTIBODY TEST NEGATIVE	24	5	9.51	4.36	1.66	11.41	24	5	9.53	4.36	1.66	11.42
INJECTION SITE PLISTCLE	36	10	11.29	3.27	1.62	6.58	36	10	11.31	3.27	1.62	6.59
VACCINATION SITE INFLAMMATION	155	66	27.08	2.13	1.60	2.84	155	65	28.00	2.17	1.62	2.89
VACCINATION SITE CELLULITIS	42	13	11.69	2.93	1.57	5.46	42	13	11.71	2.93	1.57	5.46
INJECTION SITE MACULE	22	5	8.01	3.99	1.51	10.54	22	5	8.02	3.99	1.51	10.55
INJECTION SITE SCAR	37	12	9.56	2.80	1.46	5.36	37	12	9.58	2.80	1.46	5.37
INJECTION SITE EXTRAVASATION	91	39	15.40	2.12	1.45	3.08	91	39	15.43	2.12	1.46	3.08
MASS EXCISION	16	3	6.47	4.84	1.41	16.61	16	3	6.48	4.84	1.41	16.62
INJECTION SITE LYMPHADENOPATHY	82	37	12.31	2.01	1.36	2.96	82	36	13.13	2.07	1.40	3.06
INJECTION SITE SCAB	57	25	8.92	2.07	1.29	3.31	57	25	8.94	2.07	1.29	3.31
LIMB IMMOBILISATION	31	11	6.86	2.56	1.29	5.09	31	11	6.88	2.56	1.29	5.09
EYE COLOUR CHANGE	19	5	5.85	3.45	1.29	9.23	19	5	5.86	3.45	1.29	9.24
VACCINATION SITE SCAR	25	8	6.30	2.84	1.28	6.29	25	8	6.31	2.84	1.28	6.29
GINGIVITIS	21	6	5.98	3.18	1.28	7.87	20	6	5.32	3.03	1.22	7.54
URINE OUTPUT INCREASED	21	6	5.98	3.18	1.28	7.87	21	6	5.99	3.18	1.28	7.87
FEELING OF RELAXATION	26	9	5.86	2.62	1.23	5.59	26	9	5.87	2.62	1.23	5.60

EPIDEMIOLOGY	35	14	6.35	2.27	1.22	4.22	34	14	5.81	2.20	1.18	4.11
GENERALISED OEDEMA	22	7	5.48	2.85	1.22	6.68	22	7	5.49	2.85	1.22	6.68
PIXY/TOM LIMB SYNDROME	22	7	5.48	2.85	1.22	6.68	22	7	5.49	2.85	1.22	6.68
MULTIPLE USE OF SINGLE-USE PRODUCT	14	3	4.96	4.23	1.22	14.73	14	3	4.97	4.24	1.22	14.74
DENTAL DISCOMFORT	36	15	6.03	2.18	1.19	3.98	36	15	6.05	2.18	1.19	3.98
MYOSCLEROSIS	36	15	6.03	2.18	1.19	3.98	36	15	6.05	2.18	1.19	3.98
SKIN PLAQUE	28	11	5.11	2.31	1.15	4.64	28	11	5.12	2.31	1.15	4.64
ABSCESS LIMB	17	5	4.49	3.08	1.14	8.36	17	5	4.50	3.09	1.14	8.37
ECZEMA NUMMULAR	15	4	4.35	3.40	1.13	10.25	15	4	4.35	3.40	1.13	10.26
SKIN HYPERTROPHY	20	7	4.24	2.59	1.10	6.13	20	7	4.25	2.59	1.10	6.13
ACCIDENTAL UNDERDOSE	204	1	180.39	185.09	25.95	1320.29	201	1	177.79	182.50	25.58	1301.87
VACCINATION SITE DYSAESTHESIA	20	1	13.76	18.15	2.44	135.21	20	1	13.77	18.16	2.44	135.50
PRODUCT CONTAMINATION PHYSICAL	19	1	12.88	17.24	2.31	128.77	19	1	12.89	17.25	2.31	128.86
VACCINATION SITE ANAESTHESIA	19	1	12.88	17.24	2.31	128.77	19	1	12.89	17.25	2.31	128.86
VACCINATION SITE HYPERSENSITIVITY	16	2	8.19	7.26	1.67	31.57	16	2	8.20	7.26	1.67	31.59
PRODUCT EXPIRATION DATE ISSUE	13	2	5.74	5.90	1.33	26.13	13	2	5.75	5.90	1.33	26.15
SARS-COV-2 ANTIBODY TEST	11	1	5.92	9.98	1.29	77.30	11	1	5.92	9.99	1.29	77.36
VACCINATION SITE STREAKING	11	2	4.19	4.99	1.11	22.51	11	2	4.19	4.99	1.11	22.53
VACCINATION SITE NODULE	85	39	12.28	1.98	1.35	2.89	84	38	12.57	2.01	1.37	2.94
TOOTH LOSS	14	4	3.68	3.18	1.05	9.65	14	3	4.97	4.24	1.22	14.74
INJECTION RELATED REACTION	17	6	3.44	2.57	1.01	6.52	17	4	5.76	3.86	1.30	11.47

**Primary Domestic VAERS COVID-19 Reports by Jurisdiction and Severity
Vaccinated and Received: December 14, 2020 - 04/22/2022 or missing
VAERS reports as of 04/22/2022 at 3PM
(N=810843)**

1

Jurisdiction	Estimated Population ^{1,2}	Death Reports ⁴ N(%)	Non-Death Serious Reports ⁵ N(%)	Non-Serious Reports N(%)	All Reports N
Alaska	731,545	34 (1.4)	105 (4.4)	2,242 (94.2)	2381
Alabama	4,903,185	86 (1.2)	424 (5.9)	6,632 (92.9)	7142
Arkansas	3,017,804	106 (2.2)	585 (12.3)	4,063 (85.5)	4754
Arizona	7,278,717	133 (0.8)	1,024 (6.1)	15,659 (93.1)	16816
California	39,512,223	646 (0.8)	4,830 (6.2)	72,107 (92.9)	77583
Colorado	5,758,736	121 (0.8)	1,196 (8.1)	13,419 (91.1)	14736
Connecticut	3,565,287	71 (0.7)	639 (6.2)	9,675 (93.2)	10385
District of Columbia	705,749	18 (0.9)	119 (5.9)	1,872 (93.2)	2009
Delaware	973,764	22 (1.0)	162 (7.4)	2,008 (91.6)	2192
Florida	21,477,737	522 (1.2)	4,264 (9.5)	39,971 (89.3)	44757
Georgia	10,617,423	342 (1.8)	1,444 (7.8)	16,740 (90.4)	18526
Hawaii	1,415,872	42 (1.4)	198 (6.6)	2,769 (92.0)	3009
Iowa	3,155,070	103 (1.7)	569 (9.5)	5,297 (88.7)	5969
Idaho	1,787,065	29 (0.8)	235 (6.4)	3,391 (92.8)	3655
Illinois	12,671,821	344 (1.4)	2,189 (8.6)	22,847 (90.0)	25380
Indiana	6,732,219	159 (0.6)	831 (3.1)	25,641 (96.3)	26631
Kansas	2,913,314	81 (1.4)	401 (6.9)	5,324 (91.7)	5806
Kentucky	4,467,673	743 (6.4)	1,902 (16.3)	9,024 (77.3)	11669
Louisiana	4,648,794	77 (1.2)	431 (6.8)	5,845 (92.0)	6353
Massachusetts	6,892,503	149 (0.8)	1,268 (7.0)	16,724 (92.2)	18141
Maryland	6,045,680	136 (0.9)	1,218 (7.9)	13,988 (91.2)	15342
Maine	1,344,212	39 (1.0)	241 (6.1)	3,675 (92.9)	3955
Michigan	9,986,857	662 (2.4)	5,892 (21.6)	20,764 (76.0)	27318
Minnesota	5,639,632	461 (2.6)	3,383 (18.8)	14,153 (78.6)	17997
Missouri	6,137,428	264 (2.1)	1,244 (10.0)	10,972 (87.9)	12480

¹ Source for Estimated State Data: <https://www.census.gov/data/tables/time-series/demo/popest/2010s-state-total.html>

² Source for 2018 Estimated Freely Associated States and Guam Data: <https://sdd.spc.int/>

³ Source for 2020 Estimated US Virgin Islands Data: <https://www.worldometers.info/world-population/united-states-virgin-islands-population/>

⁴ Death Reports include unconfirmed reports of death. Some cases are pending confirmation by autopsy, medical record, or death certificate (VAERS form Item 21)

⁵ Non-Death Serious reports include reports of life-threatening conditions, hospitalization, extended hospitalization, permanent disability, or birth defect (VAERS form Item 21)

**Primary Domestic VAERS COVID-19 Reports by Jurisdiction and Severity
Vaccinated and Received: December 14, 2020 - 04/22/2022 or missing
VAERS reports as of 04/22/2022 at 3PM
(N=810843)**

Jurisdiction	Estimated Population^{1,2}	Death Reports⁴ N(%)	Non-Death Serious Reports⁵ N(%)	Non-Serious Reports N(%)	All Reports N
Mississippi	2,976,149	63 (1.8)	199 (5.7)	3,221 (92.5)	3483
Montana	1,068,778	114 (3.6)	543 (17.0)	2,539 (79.4)	3196
North Carolina	10,488,084	168 (0.8)	1,475 (7.4)	18,298 (91.8)	19941
North Dakota	762,062	39 (2.3)	297 (17.5)	1,365 (80.2)	1701
Nebraska	1,934,408	58 (1.6)	280 (7.8)	3,233 (90.5)	3571
New Hampshire	1,359,711	84 (2.1)	292 (7.4)	3,581 (90.5)	3957
New Jersey	8,882,190	199 (0.9)	1,757 (7.6)	21,286 (91.6)	23242
New Mexico	2,096,829	51 (1.1)	239 (5.2)	4,342 (93.7)	4632
Nevada	3,080,156	45 (0.8)	430 (8.1)	4,847 (91.1)	5322
New York	19,453,561	380 (0.9)	3,084 (7.2)	39,517 (91.9)	42981
Ohio	11,689,100	332 (1.4)	2,062 (8.6)	21,587 (90.0)	23981
Oklahoma	3,956,971	138 (1.8)	611 (7.8)	7,065 (90.4)	7814
Oregon	4,217,737	86 (0.8)	740 (7.0)	9,815 (92.2)	10641
Pennsylvania	12,801,989	296 (1.0)	2,057 (7.3)	25,888 (91.7)	28241
Rhode Island	1,059,361	21 (0.8)	163 (6.4)	2,376 (92.8)	2560
South Carolina	5,148,714	75 (0.9)	569 (7.0)	7,432 (92.0)	8076
South Dakota	884,659	175 (10.4)	109 (6.5)	1,399 (83.1)	1683
Tennessee	6,829,174	906 (7.4)	954 (7.8)	10,382 (84.8)	12242
Texas	28,995,881	731 (1.6)	2,906 (6.5)	40,977 (91.8)	44614
Utah	3,205,958	38 (0.7)	359 (6.6)	5,081 (92.8)	5478
Virginia	8,535,519	163 (0.9)	1,285 (6.9)	17,123 (92.2)	18571
Vermont	623,989	15 (0.7)	108 (5.2)	1,947 (94.1)	2070
Washington	7,614,893	214 (1.1)	1,478 (7.7)	17,440 (91.2)	19132
Wisconsin	5,822,434	410 (2.9)	1,389 (9.8)	12,382 (87.3)	14181
West Virginia	1,792,147	67 (2.2)	296 (9.7)	2,685 (88.1)	3048

¹ Source for Estimated State Data: <https://www.census.gov/data/tables/time-series/demo/popest/2010s-state-total.html>

² Source for 2018 Estimated Freely Associated States and Guam Data: <https://sdd.spc.int/>

³ Source for 2020 Estimated US Virgin Islands Data: <https://www.worldometers.info/world-population/united-states-virgin-islands-population/>

⁴ Death Reports include unconfirmed reports of death. Some cases are pending confirmation by autopsy, medical record, or death certificate (VAERS form Item 21)

⁵ Non-Death Serious reports include reports of life-threatening conditions, hospitalization, extended hospitalization, permanent disability, or birth defect (VAERS form Item 21)

Primary Domestic VAERS COVID-19 Reports by Jurisdiction and Severity
Vaccinated and Received: December 14, 2020 - 04/22/2022 or missing
VAERS reports as of 04/22/2022 at 3PM
(N=810843)

Jurisdiction	Estimated Population¹²³	Death Reports⁴ N(%)	Non-Death Serious Reports⁵ N(%)	Non-Serious Reports N(%)	All Reports N
Wyoming	578,759	24 (2.4)	76 (7.7)	890 (89.9)	990
Not Specified	NA	2,865 (2.7)	10,191 (9.6)	92,799 (87.7)	105855
United States	328,239,523	13,147 (1.6)	68,743 (8.5)	724,299 (89.8)	806189
American Samoa	56,700	1 (3.0)	2 (6.1)	30 (90.9)	33
Federated States of Micronesia	105,300		2 (40.0)	3 (60.0)	5
Guam	172,400	4 (2.4)	15 (9.0)	148 (88.6)	167
Republic of the Marshall Islands	55,500		1 (16.7)	5 (83.3)	6
Commonwealth of the Northern Mariana Islands	56,200	11 (28.9)	5 (13.2)	22 (57.9)	38
Puerto Rico	3,193,694	118 (2.7)	162 (3.8)	4,022 (93.5)	4302
Republic of Palau	17,900			2 (100.0)	2
QM	NA			2 (100.0)	2
QW	NA			1 (100.0)	1
Tx	NA			1 (100.0)	1
U.S. Virgin Islands	104,433		6 (6.5)	87 (93.5)	93
XB	NA		1 (50.0)	1 (50.0)	2
XV	NA		1 (50.0)	1 (50.0)	2

¹ Source for Estimated State Data: <https://www.census.gov/data/tables/time-series/demo/popest/2010s-state-total.html>

² Source for 2018 Estimated Freely Associated States and Guam Data: <https://sdd.spc.int/>

³ Source for 2020 Estimated US Virgin Islands Data: <https://www.worldometers.info/world-population/united-states-virgin-islands-population/>

⁴ Death Reports include unconfirmed reports of death. Some cases are pending confirmation by autopsy, medical record, or death certificate (VAERS form Item 21)

⁵ Non-Death Serious reports include reports of life-threatening conditions, hospitalization, extended hospitalization, permanent disability, or birth defect (VAERS form Item 21)

VAERS Pre-specified Conditions for COVID19 Reports, Automated Data (non-reviewed)
Initial domestic reports only, VAERS reports as of 04/22/2022 at 3PM

1

Condition	Age group							Total
	0-17	18-49	50-64	65-74	75-84	85+	UNK	
Acute Myocardial Infarction	20(00.6%)	680(20.3%)	812(24.2%)	777(23.2%)	535(16.0%)	310(09.3%)	217(06.5%)	3351
Anaphylaxis	83(03.1%)	1433(53.4%)	667(24.9%)	213(07.9%)	66(02.5%)	11(00.4%)	210(07.8%)	2683
Appendicitis	81(09.3%)	474(54.2%)	188(21.5%)	78(08.9%)	19(02.2%)	3(00.3%)	31(03.5%)	874
Bells Palsy	139(02.2%)	2437(39.4%)	1747(28.2%)	944(15.3%)	418(06.8%)	200(03.2%)	300(04.9%)	6185
COVID19								.
Coagulopathy	157(01.3%)	3669(30.3%)	3171(26.2%)	2317(19.1%)	1271(10.5%)	502(04.1%)	1016(08.4%)	12103
Death	71(00.5%)	1042(07.3%)	2208(15.5%)	3216(22.6%)	3499(24.6%)	2985(21.0%)	1179(08.3%)	14200
Guillian-Barre Syndrome	32(02.9%)	375(33.6%)	330(29.5%)	177(15.8%)	86(07.7%)	16(01.4%)	101(09.0%)	1117
Kawasaki Disease	12(80.0%)	2(13.3%)		1(06.7%)				15
Multisystem Inflammatory Syndrome in Adults		80(25.1%)	65(20.4%)	94(29.5%)	54(16.9%)	26(08.2%)		319
Multisystem Inflammatory Syndrome in Children	158(89.8%)	18(10.2%)						176
Myopericarditis	875(18.9%)	2464(53.1%)	604(13.0%)	293(06.3%)	111(02.4%)	21(00.5%)	273(05.9%)	4641
Narcolepsy	2(04.4%)	16(35.6%)	12(26.7%)	7(15.6%)	1(02.2%)	1(02.2%)	6(13.3%)	45
Pregnant	108(01.2%)	7415(80.7%)	431(04.7%)	270(02.9%)	103(01.1%)	32(00.3%)	832(09.1%)	9191
Seizure	752(11.6%)	3564(55.1%)	968(15.0%)	518(08.0%)	284(04.4%)	127(02.0%)	259(04.0%)	6472
Stroke	32(00.7%)	758(15.6%)	1227(25.3%)	1119(23.1%)	860(17.7%)	466(09.6%)	390(08.0%)	4852
Transverse Myelitis	4(01.5%)	110(40.4%)	70(25.7%)	35(12.9%)	20(07.4%)	5(01.8%)	28(10.3%)	272
V-safe Serious	23(01.2%)	646(32.4%)	659(33.0%)	482(24.1%)	149(07.5%)	30(01.5%)	7(00.4%)	1996

**Primary Domestic VAERS COVID-19 Reports by Jurisdiction and Severity
Vaccinated and Received: December 14, 2020 - 04/29/2022 or missing
VAERS reports as of 04/29/2022 at 3PM
(N=813683)**

1

Jurisdiction	Estimated Population ^{1,2}	Death Reports ⁴ N(%)	Non-Death Serious Reports ⁵ N(%)	Non-Serious Reports N(%)	All Reports N
Alaska	731,545	34 (1.4)	105 (4.4)	2,241 (94.2)	2380
Alabama	4,903,185	86 (1.2)	424 (5.9)	6,651 (92.9)	7161
Arkansas	3,017,804	106 (2.2)	584 (12.3)	4,070 (85.5)	4760
Arizona	7,278,717	133 (0.8)	1,030 (6.1)	15,679 (93.1)	16842
California	39,512,223	648 (0.8)	4,854 (6.2)	72,249 (92.9)	77751
Colorado	5,758,736	121 (0.8)	1,207 (8.1)	13,572 (91.1)	14900
Connecticut	3,565,287	71 (0.7)	642 (6.2)	9,695 (93.1)	10408
District of Columbia	705,749	18 (0.9)	120 (6.0)	1,866 (93.1)	2004
Delaware	973,764	22 (1.0)	162 (7.3)	2,021 (91.7)	2205
Florida	21,477,737	524 (1.2)	4,298 (9.6)	40,020 (89.2)	44842
Georgia	10,617,423	342 (1.8)	1,455 (7.8)	16,759 (90.3)	18556
Hawaii	1,415,872	42 (1.4)	199 (6.6)	2,766 (92.0)	3007
Iowa	3,155,070	107 (1.8)	573 (9.6)	5,299 (88.6)	5979
Idaho	1,787,065	29 (0.8)	235 (6.4)	3,409 (92.8)	3673
Illinois	12,671,821	347 (1.4)	2,216 (8.7)	22,932 (89.9)	25495
Indiana	6,732,219	159 (0.6)	835 (3.1)	25,640 (96.3)	26634
Kansas	2,913,314	81 (1.4)	404 (6.9)	5,341 (91.7)	5826
Kentucky	4,467,673	750 (6.4)	1,905 (16.3)	9,050 (77.3)	11705
Louisiana	4,648,794	77 (1.2)	438 (6.9)	5,848 (91.9)	6363
Massachusetts	6,892,503	150 (0.8)	1,271 (6.8)	17,307 (92.4)	18728
Maryland	6,045,680	137 (0.9)	1,218 (7.9)	14,074 (91.2)	15429
Maine	1,344,212	39 (1.0)	243 (6.1)	3,678 (92.9)	3960
Michigan	9,986,857	665 (2.4)	5,939 (21.7)	20,799 (75.9)	27403
Minnesota	5,639,632	463 (2.6)	3,408 (18.9)	14,168 (78.5)	18039
Missouri	6,137,428	265 (2.1)	1,258 (10.1)	10,991 (87.8)	12514

¹ Source for Estimated State Data: <https://www.census.gov/data/tables/time-series/demo/popest/2010s-state-total.html>

² Source for 2018 Estimated Freely Associated States and Guam Data: <https://sdd.spc.int/>

³ Source for 2020 Estimated US Virgin Islands Data: <https://www.worldometers.info/world-population/united-states-virgin-islands-population/>

⁴ Death Reports include unconfirmed reports of death. Some cases are pending confirmation by autopsy, medical record, or death certificate (VAERS form Item 21)

⁵ Non-Death Serious reports include reports of life-threatening conditions, hospitalization, extended hospitalization, permanent disability, or birth defect (VAERS form Item 21)

**Primary Domestic VAERS COVID-19 Reports by Jurisdiction and Severity
Vaccinated and Received: December 14, 2020 - 04/29/2022 or missing
VAERS reports as of 04/29/2022 at 3PM
(N=813683)**

Jurisdiction	Estimated Population^{1,2}	Death Reports⁴ N(%)	Non-Death Serious Reports⁵ N(%)	Non-Serious Reports N(%)	All Reports N
Mississippi	2,976,149	64 (1.8)	201 (5.7)	3,254 (92.5)	3519
Montana	1,068,778	115 (3.6)	542 (17.0)	2,537 (79.4)	3194
North Carolina	10,488,084	169 (0.8)	1,484 (7.4)	18,310 (91.7)	19963
North Dakota	762,062	39 (2.3)	297 (17.5)	1,360 (80.2)	1696
Nebraska	1,934,408	59 (1.6)	280 (7.8)	3,250 (90.6)	3589
New Hampshire	1,359,711	84 (2.1)	293 (7.4)	3,596 (90.5)	3973
New Jersey	8,882,190	200 (0.9)	1,768 (7.6)	21,339 (91.6)	23307
New Mexico	2,096,829	51 (1.1)	241 (5.2)	4,347 (93.7)	4639
Nevada	3,080,156	48 (0.9)	430 (8.1)	4,861 (91.0)	5339
New York	19,453,561	384 (0.9)	3,098 (7.2)	39,574 (91.9)	43056
Ohio	11,689,100	336 (1.4)	2,076 (8.6)	21,624 (90.0)	24036
Oklahoma	3,956,971	138 (1.8)	609 (7.8)	7,076 (90.5)	7823
Oregon	4,217,737	86 (0.8)	743 (6.9)	9,894 (92.3)	10723
Pennsylvania	12,801,989	296 (1.0)	2,068 (7.3)	25,927 (91.6)	28291
Rhode Island	1,059,361	21 (0.8)	166 (6.5)	2,371 (92.7)	2558
South Carolina	5,148,714	75 (0.9)	573 (7.1)	7,449 (92.0)	8097
South Dakota	884,659	195 (11.5)	108 (6.3)	1,398 (82.2)	1701
Tennessee	6,829,174	923 (7.5)	956 (7.8)	10,393 (84.7)	12272
Texas	28,995,881	735 (1.6)	2,928 (6.5)	41,125 (91.8)	44788
Utah	3,205,958	39 (0.7)	360 (6.6)	5,082 (92.7)	5481
Virginia	8,535,519	163 (0.9)	1,290 (6.9)	17,170 (92.2)	18623
Vermont	623,989	15 (0.7)	109 (5.2)	1,955 (94.0)	2079
Washington	7,614,893	215 (1.1)	1,488 (7.8)	17,482 (91.1)	19185
Wisconsin	5,822,434	410 (2.9)	1,395 (9.8)	12,400 (87.3)	14205
West Virginia	1,792,147	67 (2.2)	297 (9.7)	2,685 (88.1)	3049

¹ Source for Estimated State Data: <https://www.census.gov/data/tables/time-series/demo/popest/2010s-state-total.html>

² Source for 2018 Estimated Freely Associated States and Guam Data: <https://sdd.spc.int/>

³ Source for 2020 Estimated US Virgin Islands Data: <https://www.worldometers.info/world-population/united-states-virgin-islands-population/>

⁴ Death Reports include unconfirmed reports of death. Some cases are pending confirmation by autopsy, medical record, or death certificate (VAERS form Item 21)

⁵ Non-Death Serious reports include reports of life-threatening conditions, hospitalization, extended hospitalization, permanent disability, or birth defect (VAERS form Item 21)

Primary Domestic VAERS COVID-19 Reports by Jurisdiction and Severity
Vaccinated and Received: December 14, 2020 - 04/29/2022 or missing
VAERS reports as of 04/29/2022 at 3PM
(N=813683)

Jurisdiction	Estimated Population¹²³	Death Reports⁴ N(%)	Non-Death Serious Reports⁵ N(%)	Non-Serious Reports N(%)	All Reports N
Wyoming	578,759	24 (2.4)	77 (7.8)	892 (89.8)	993
Not Specified	NA	2,897 (2.7)	10,267 (9.7)	93,129 (87.6)	106293
United States	328,239,523	13,264 (1.6)	69,167 (8.5)	726,605 (89.8)	809036
American Samoa	56,700	1 (3.0)	2 (6.1)	30 (90.9)	33
Federated States of Micronesia	105,300		2 (33.3)	4 (66.7)	6
Guam	172,400	4 (2.4)	15 (8.9)	149 (88.7)	168
Republic of the Marshall Islands	55,500		1 (16.7)	5 (83.3)	6
Commonwealth of the Northern Mariana Islands	56,200	11 (28.9)	5 (13.2)	22 (57.9)	38
Puerto Rico	3,193,694	118 (2.7)	162 (3.8)	4,012 (93.5)	4292
Republic of Palau	17,900			2 (100.0)	2
QM	NA			2 (100.0)	2
QW	NA			1 (100.0)	1
Tx	NA			1 (100.0)	1
U.S. Virgin Islands	104,433		6 (6.4)	88 (93.6)	94
XB	NA		1 (50.0)	1 (50.0)	2
XV	NA		1 (50.0)	1 (50.0)	2

¹ Source for Estimated State Data: <https://www.census.gov/data/tables/time-series/demo/popest/2010s-state-total.html>

² Source for 2018 Estimated Freely Associated States and Guam Data: <https://sdd.spc.int/>

³ Source for 2020 Estimated US Virgin Islands Data: <https://www.worldometers.info/world-population/united-states-virgin-islands-population/>

⁴ Death Reports include unconfirmed reports of death. Some cases are pending confirmation by autopsy, medical record, or death certificate (VAERS form Item 21)

⁵ Non-Death Serious reports include reports of life-threatening conditions, hospitalization, extended hospitalization, permanent disability, or birth defect (VAERS form Item 21)

PREFERRED Medical Dictionary for Regulatory Activities (MedDRA) Terms (VAERS-1 Box 7, VAERS 2.0 Box 18)

For Current Week and Past Week Comparison

Following **ALL 12/14/2020-04/29/2022 COVID19 Pfizer Ages 18+ Vaccines**

Compared to **ALL 12/14/2020-04/29/2022 COVID19 Moderna Ages 18+ Vaccines**

AGES 18+ YEARS, Initial domestic reports only, VAERS reports as of 04/29/2022

Vaccination, Received, and Completed Date: 12/14 - 04/29 (Current Week) and 12/14 - 04/22 (Past Week)

N $\geq$ 3 (Current Week), PRR $\geq$ 2.00 (Ratio of Proportions), Chi-Square $\geq$ 4.00

MedDRA PTs sorting based on lower confidence limit and PFIZER adverse event count from 12/14/2020-04/29/2022

AGES 18+ YEARS excludes missing ages

MedDRA Codes ALL Reports (18+)	12/14/2020- 04/29/2022 PFIZER N=304871	12/14/2020- 04/29/2022 MODERNA N=326103	12/14-04/29 Chi-Square	12/14-04/29 PRR	12/14-04/29 LCL	12/14-04/29 UCL	12/14/2020- 04/22/2022 PFIZER N=303997	12/14/2020- 04/22/2022- 04/22/2022 MODERNA N=324518	12/14-04/22 Chi-Square	12/14-04/22 PRR	12/14-04/22 LCL	12/14-04/22 UCL
PRODUCT PREPARATION ERROR	562	16	552.35	37.57	22.86	61.75	561	15	552.97	39.92	23.91	66.67
VACCINATION FAILURE	1025	59	927.88	18.58	14.29	24.16	1006	60	903.07	17.90	13.79	23.22
PRODUCT PREPARATION ISSUE	2105	166	1795.31	13.56	11.58	15.88	2102	166	1788.02	13.52	11.54	15.83
DISEASE RECURRENCE	217	11	198.67	21.10	11.51	38.67	216	11	197.17	20.96	11.44	38.42
PRODUCT USE ISSUE	448	29	395.72	16.52	11.35	24.05	437	29	383.24	16.09	11.05	23.42
IMMUNISATION	2525	215	2115.87	12.56	10.93	14.44	2523	215	2108.84	12.53	10.90	14.40
OFF LABEL USE	1003	211	571.74	5.08	4.38	5.90	986	211	553.94	4.99	4.30	5.79
CIRCUMSTANCE OR INFORMATION CAPABLE OF LEADING TO MEDICATION ERROR	124	19	82.91	6.98	4.31	11.31	124	19	82.69	6.97	4.30	11.29
IMMUNODEFICIENCY	486	113	257.27	4.60	3.75	5.65	483	112	255.39	4.60	3.75	5.65
DRUG INEFFECTIVE	1086	276	538.29	4.21	3.69	4.80	1061	272	520.36	4.16	3.65	4.76
APPARENT LIFE THREATENING EVENT	64	10	41.66	6.85	3.52	13.33	64	10	41.55	6.83	3.51	13.30
INCORRECT PRODUCT FORMULATION ADMINISTERED	545	160	236.33	3.64	3.05	4.35	547	162	234.32	3.60	3.03	4.29
MIDDLE INSOMNIA	78	17	42.09	4.91	2.90	8.29	77	17	41.03	4.84	2.86	8.18
OVERDOSE	176	58	66.74	3.25	2.41	4.37	177	56	69.99	3.37	2.50	4.56
NEAR DEATH EXPERIENCE	109	35	42.14	3.33	2.28	4.87	108	35	41.16	3.29	2.25	4.82
INTERCHANGE OF VACCINE PRODUCTS	5786	2651	1404.98	2.33	2.23	2.44	5790	2644	1407.48	2.34	2.23	2.45
WHITE BLOOD CELL COUNT INCREASED	113	38	41.47	3.18	2.20	4.59	113	37	42.61	3.26	2.25	4.73
CROHN'S DISEASE	130	48	42.57	2.90	2.08	4.03	128	47	42.04	2.91	2.08	4.06
ANTINUCLEAR ANTIBODY POSITIVE	30	7	14.62	4.58	2.01	10.44	30	7	14.57	4.58	2.01	10.42
SKIN DISORDER	276	122	69.69	2.42	1.96	2.99	272	120	68.56	2.42	1.95	3.00
POLYMENORRHOEA	463	220	103.03	2.25	1.92	2.64	462	220	101.85	2.24	1.91	2.63
UTERINE HAEMORRHAGE	64	22	22.43	3.11	1.92	5.05	64	22	22.34	3.11	1.91	5.04
EXPOSURE TO SARS-COV-2	1264	645	244.83	2.10	1.91	2.30	1251	629	248.69	2.12	1.93	2.34
DRUG HYPERSENSITIVITY	182	78	48.10	2.50	1.91	3.25	181	77	48.19	2.51	1.92	3.28
MENSTRUAL DISORDER	1600	830	299.35	2.06	1.90	2.24	1598	829	297.23	2.06	1.89	2.24
EAR DISORDER	112	45	32.41	2.66	1.88	3.76	111	44	32.62	2.69	1.90	3.82
VIBRATORY SENSE INCREASED	69	25	22.70	2.95	1.87	4.66	66	25	20.32	2.82	1.78	4.47
CLAUSTROPHOBIA	23	5	11.51	4.92	1.87	12.94	23	5	11.47	4.91	1.87	12.92
INTERMENSTRUAL BLEEDING	869	451	161.81	2.06	1.84	2.31	866	449	160.68	2.06	1.84	2.31
HYPOMENORRHOEA	116	49	31.07	2.53	1.81	3.54	116	49	30.93	2.53	1.81	3.53
STRIDOR	125	54	32.33	2.48	1.80	3.41	124	54	31.49	2.45	1.78	3.37
PHARYNGEAL INFLAMMATION	17	3	9.36	6.06	1.78	20.68	17	3	9.33	6.05	1.77	20.64
ELECTROCARDIOGRAM ABNORMAL	77	31	21.93	2.66	1.75	4.03	77	31	21.83	2.65	1.75	4.02

HAEMOGLOBIN DECREASED	72	29	20.43	2.66	1.73	4.09	71	29	19.62	2.61	1.70	4.03
BLOOD LACTIC ACID INCREASED	19	4	9.50	5.08	1.73	34.93	19	4	9.47	5.07	1.73	14.90
APPENDICITIS	410	217	72.58	2.02	1.71	72.58	410	217	72.15	2.02	1.71	2.38
SUSPECTED COVID-19	351	184	63.41	2.04	1.71	2.44	341	182	58.72	2.00	1.67	2.39
MAST CELL ACTIVATION SYNDROME	49	18	15.55	2.91	1.70	5.00	49	18	15.48	2.91	1.69	1.99
FIBRIN D DIMER INCREASED	101	45	24.62	2.40	1.69	3.41	100	45	23.82	2.37	1.67	3.37
UPPER RESPIRATORY TRACT CONGESTION	101	45	24.62	2.40	1.69	3.41	101	44	25.47	2.45	1.72	3.49
PERITONITIS	34	11	12.30	3.31	1.68	6.52	33	11	11.45	3.20	1.62	6.34
VACCINATION SITE	50	19	15.16	2.81	1.66	4.77	50	19	15.09	2.81	1.66	4.76
HYPOAESTHESIA	44	16	14.05	2.94	1.66	5.21	44	16	13.99	2.94	1.66	5.20
NORMAL LABOUR	40	14	13.33	3.06	1.66	5.02	40	13	14.53	3.28	1.76	6.14
BONE DISORDER	16	3	8.42	5.70	1.66	19.58	16	3	8.39	5.69	1.66	19.54
ANGIOGRAM	140	68	29.39	2.20	1.65	2.94	140	66	30.90	2.26	1.69	3.03
NERVE COMPRESSION	25	7	10.22	3.82	1.65	8.83	25	7	10.19	3.81	1.65	8.81
WEIGHT FLUCTUATION	31	10	11.16	3.32	1.63	6.76	30	10	10.32	3.20	1.57	6.55
RED BLOOD CELL COUNT DECREASED	29	9	10.83	3.45	1.63	7.28	29	9	10.79	3.44	1.63	7.27
LIVE BIRTH	93	43	21.13	2.31	1.61	3.32	91	42	20.63	2.31	1.60	3.33
BASEDOW'S DISEASE	202	108	34.57	2.00	1.58	2.53	200	106	34.72	2.01	1.59	2.55
DELIVERY	59	25	15.30	2.52	1.58	4.03	59	25	15.23	2.52	1.58	4.02
WHITE BLOOD CELL COUNT INCREASED	24	7	9.38	3.67	1.58	8.51	24	7	9.35	3.66	1.58	8.49
WOUND DRAINAGE	89	42	19.42	2.27	1.57	3.37	89	42	19.32	2.26	1.57	3.36
SUPPRESSED LACTATION	36	13	11.43	2.96	1.57	5.58	35	13	10.62	2.87	1.52	5.43
OSTEOPENIA	78	36	17.66	2.32	1.56	3.44	78	36	17.57	2.31	1.56	3.43
BLOOD CHOLESTEROL INCREASED	69	31	16.31	2.38	1.56	3.64	71	30	18.58	2.53	1.65	3.87
FACIAL SPASM	115	58	22.12	2.12	1.55	2.91	115	57	22.83	2.15	1.57	2.96
BODY TEMPERATURE ABNORMAL	58	25	14.60	2.48	1.55	3.97	57	25	13.85	2.43	1.52	3.89
ABNORMAL UTERINE BLEEDING	15	3	7.49	5.35	1.55	3.35	14	3	6.56	4.98	1.43	17.33
COLOSTOMY	15	3	7.49	5.35	1.55	3.35	14	3	6.56	4.98	1.43	17.33
PHARYNGEAL MASS	15	3	7.49	5.35	1.55	3.35	15	3	7.47	5.34	1.55	18.44
PNEUMONIA PNEUMONAL	15	3	7.49	5.35	1.55	3.35	15	3	7.47	5.34	1.55	18.44
SLEEP DISORDER DUE TO A GENERAL MEDICAL CONDITION	15	3	7.49	5.35	1.55	3.35	14	3	6.56	4.98	1.43	17.33
PUPILLARY REFLEX IMPAIRED	66	30	15.24	2.25	1.53	3.62	65	30	14.51	2.31	1.50	3.56
ENDOTRACHEAL INTUBATION COMPLICATION	17	4	7.70	4.55	1.53	13.51	17	4	7.67	4.54	1.53	13.48
APPENDICITIS PERFORATED	76	36	16.35	2.26	1.52	3.36	76	36	16.27	2.25	1.52	3.35
HANGOVER	62	28	14.44	2.37	1.52	3.70	59	28	12.41	2.25	1.43	3.53
BLOOD BILIRUBIN INCREASED	25	8	8.88	3.34	1.51	7.41	25	8	8.85	3.34	1.50	7.40
OVARIAN CYST	97	49	18.48	2.12	1.50	2.99	95	49	17.18	2.07	1.47	2.92
COMA SCALE ABNORMAL	75	36	15.71	2.23	1.50	3.32	74	36	15.00	2.19	1.47	3.27
CEREBROVASCULAR DISORDER	36	14	10.30	2.75	1.48	5.10	36	13	11.38	2.96	1.57	5.57
BLADDER DISORDER	53	24	12.17	2.36	1.46	3.83	53	24	12.11	2.36	1.46	3.82
GASTRIC DISORDER	102	54	17.52	2.02	1.45	2.81	102	53	18.19	2.05	1.47	2.86
RED BLOOD CELL SEDIMENTATION RATE INCREASED	37	15	9.97	2.64	1.45	4.81	37	15	9.92	2.63	1.45	4.80
ANKYLOSING SPONDYLITIS	28	10	8.80	2.99	1.45	6.17	27	10	8.01	2.88	1.40	5.95
VENTRICULAR ARRHYTHMIA	26	9	8.44	3.09	1.45	6.59	26	9	8.41	3.08	1.45	6.58
C-REACTIVE PROTEIN INCREASED	59	28	12.48	2.25	1.44	3.53	57	28	11.16	2.17	1.38	3.12

RENAL TRANSPLANT	22	7	7.74	3.36	1.44	7.87	21	6	8.21	3.74	1.51	9.26
NASAL PRURITUS	57	27	12.07	2.26	1.43	3.57	58	28	11.78	2.21	1.41	3.47
LACTATION DISORDER	33	13	9.19	2.72	1.43	5.16	33	12	10.25	2.94	1.52	5.68
MAGNETIC RESONANCE												
IMAGING HEART	20	6	7.41	3.57	1.43	8.88	20	6	7.38	3.56	1.43	8.86
PHARYNGEAL DISORDER	20	6	7.41	3.57	1.43	8.88	20	6	7.38	3.56	1.43	8.86
AORTIC DISORDER	18	5	7.10	3.85	1.43	10.37	18	5	7.08	3.84	1.43	10.35
HYPERAESTHESIA	18	5	7.10	3.85	1.43	10.37	18	5	7.08	3.84	1.43	10.35
NEUTROPHIL COUNT												
DECREASED	16	4	6.82	4.28	1.43	12.80	16	4	6.80	4.27	1.43	12.77
CONVALESCENT PLASMA												
TRANSFUSION	43	19	10.16	2.42	1.41	4.15	44	18	11.79	2.61	1.51	4.52
VOCAL CORD PARALYSIS	29	11	8.42	2.82	1.41	5.64	29	11	8.39	2.81	1.41	5.63
SUBMAXILLARY GLAND												
ENLARGEMENT	25	9	7.67	2.97	1.39	6.37	25	9	7.64	2.97	1.38	6.35
PROTEINURIA	60	30	11.41	2.14	1.38	3.32	60	31	10.55	2.07	1.34	3.19
WRONG PATIENT	32	13	8.47	2.63	1.38	8.43	32	13	8.43	2.63	1.38	8.43
MASTITIS	67	35	11.64	2.05	1.36	3.08	67	33	13.17	2.17	1.43	3.29
STILLBIRTH	40	18	9.09	2.38	1.36	4.15	39	18	8.39	2.31	1.32	4.04
BASAL GANGLIA INFARCTION	28	11	7.69	2.72	1.36	5.47	28	11	7.66	2.72	1.35	5.46
NONINFECTIVE ENCEPHALITIS												
ESCHERICHIA URINARY TRACT	28	11	7.69	2.72	1.36	5.47	28	11	7.66	2.72	1.35	5.46
INFECTION												
THYROIDITIS	21	7	6.95	3.21	1.36	7.55	19	7	5.41	2.90	1.22	6.89
51	25	10.00	2.18	1.35	3.52	3.52	50	25	9.34	2.14	1.32	3.45
VIRAL SEPSIS	19	6	6.60	3.39	1.35	8.48	19	6	6.58	3.38	1.35	8.46
INTRACRANIAL PRESSURE												
INCREASED	41	19	8.84	2.31	1.34	3.98	41	19	8.80	2.30	1.34	3.97
DECREASED NASOLABIAL FOLD	24	9	6.93	2.85	1.33	6.14	24	9	6.90	2.85	1.32	6.12
PIARYNGEAL ULCERATION	24	9	6.93	2.85	1.33	6.14	24	9	6.90	2.85	1.32	6.12
MEASLES	15	4	5.96	4.01	1.33	12.09	15	4	5.94	4.00	1.33	12.06
PARENTERAL NUTRITION	15	4	5.96	4.01	1.33	12.09	15	4	5.94	4.00	1.33	12.06
PHARYNGITIS STRIPTOCOCAL	60	32	9.86	2.01	1.31	3.08	60	31	10.55	2.07	1.34	3.19
COR PULMONALE	22	8	6.55	2.94	1.31	6.61	21	8	5.79	2.80	1.34	6.33
GESTATIONAL DIABETES	22	8	6.55	2.94	1.31	6.61	21	8	5.79	2.80	1.34	6.33
TIC	49	25	8.79	2.10	1.30	3.39	49	25	8.74	2.09	1.39	3.39
CIRCUMIN IMPACTION	20	7	6.18	3.06	1.29	7.23	20	6	7.38	3.56	1.43	8.86
POSTPARTUM HAEMORRHAGE	20	7	6.18	3.06	1.29	7.23	19	7	5.41	2.90	1.22	6.89
VISUAL ACUTY REDUCED	50	26	8.61	2.06	1.28	3.30	50	26	8.55	2.05	1.28	3.30
ENDOMETRIAL THICKENING	25	10	6.39	2.67	1.28	5.57	25	10	6.56	2.67	1.28	5.56
FEBRILE NEUTROPENIA	36	17	7.39	2.27	1.27	4.03	36	16	8.25	2.40	1.33	4.33
PETIT MAL EPILEPSY	28	12	6.69	2.50	1.27	4.91	28	12	6.65	2.49	1.27	4.90
WOUND INFECTION	28	12	6.69	2.50	1.27	4.91	27	12	5.99	2.40	1.22	4.74
LABILE BLOOD PRESSURE	18	6	5.82	3.21	1.27	8.08	18	6	5.79	3.20	1.37	8.07
BLOOD THYROID STIMULATING												
HORMONE INCREASED	31	14	6.82	2.37	1.26	4.45	30	13	7.05	2.46	1.29	4.72
DYSAESTHESIA	37	18	7.17	2.20	1.25	3.86	37	18	7.13	2.19	1.25	3.85
FACTOR V LEIDEN MUTATION	16	5	5.47	3.42	1.25	9.34	16	5	5.44	3.42	1.25	9.32
ANTIALI ERGIC THERAPY	32	15	6.58	2.28	1.24	4.21	32	15	6.55	2.28	1.23	4.21
PLATELET COUNT INCREASED	32	15	6.58	2.28	1.24	4.21	31	15	5.93	2.21	1.19	4.09
OCULAR ICTERUS	38	19	6.97	2.14	1.23	3.71	38	18	7.76	2.25	1.29	3.95
UTERINE PAIN	38	19	6.97	2.14	1.23	3.71	38	18	7.76	2.25	1.29	3.95
ABDOMINAL MASS	24	10	5.89	2.57	1.23	5.37	23	10	5.19	2.46	1.17	5.16
HAEMOTHORAX	14	4	5.13	3.74	1.23	11.37	14	4	5.11	3.74	1.23	11.35
POSTPARTUM STATE	14	4	5.13	3.74	1.23	11.37	14	4	5.11	3.74	1.23	11.35

THERAPEUTIC PRODUCT	14	4	5.13	3.74	1.23	11.37	14	4	5.11	3.74	1.23	11.35
EFFECT DECREASED	39	20	6.78	2.09	1.22	3.58	39	19	7.54	2.19	1.27	3.79
AZOTEMIA	30	14	6.18	2.29	1.22	4.32	30	14	6.15	2.29	1.21	4.31
CARDIAC VALVE DISEASE	19	7	5.43	2.90	1.22	6.91	19	7	5.41	2.90	1.22	6.89
VERTIBRAL ARTERY	36	18	6.57	2.14	1.21	3.77	35	18	5.94	2.08	1.18	3.66
DISSECTION	12	3	4.83	4.28	1.21	15.16	12	3	4.81	4.27	1.20	15.13
ELECTROCARDIOGRAM ST												
SEGMENT ABNORMAL												
MORPHOEA	40	21	6.60	2.04	1.20	3.46	40	21	6.56	2.03	1.20	3.45
ALANINE AMINOTRANSFERASE	40	21	6.60	2.04	1.20	3.46	40	21	6.56	2.03	1.20	3.45
INCREASED	37	19	6.38	2.08	1.20	3.62	37	19	6.34	2.08	1.20	3.61
COLIC TONY	34	17	6.16	2.14	1.20	3.83	34	17	6.13	2.14	1.19	3.82
SICK RELATIVE	34	17	6.16	2.14	1.20	3.83	34	17	6.13	2.14	1.19	3.82
FOETAL HYPOKINESIA	34	17	6.16	2.14	1.20	3.83	34	17	6.13	2.14	1.19	3.82
NIH STROKE SCALE	34	17	6.16	2.14	1.20	3.83	34	17	6.13	2.14	1.19	3.82
PNEUMOMEDIASTINUM	25	11	5.62	2.43	1.20	4.94	25	11	5.59	2.43	1.19	4.93
EYE OEDEMA	28	13	5.78	2.30	1.19	4.45	27	13	5.12	2.22	1.14	4.30
PATIENT UNCOOPERATIVE	17	6	5.05	3.03	1.19	7.69	17	6	5.03	3.02	1.19	7.67
PROTEIN URINE PRESENT	20	8	5.10	2.67	1.18	6.07	20	8	5.08	2.67	1.18	6.06
MENINGITIS VIRAL	20	8	5.10	2.67	1.18	6.07	20	8	5.08	2.67	1.18	6.06
MUSCLE RUPTURE	20	8	5.10	2.67	1.18	6.07	20	8	5.08	2.67	1.18	6.06
NECROSIS	26	12	5.37	2.32	1.17	4.59	26	12	5.34	2.31	1.17	4.58
MENISCUS INJURY												
PELVIC VENOUS THROMBOSIS	26	12	5.37	2.32	1.17	4.59	26	12	5.34	2.31	1.17	4.58
BLOOD SODIUM DECREASED	23	10	5.21	2.46	1.17	5.17	23	10	5.86	2.56	1.23	5.36
INCORRECT PRODUCT												
ADMINISTRATION DURATION	23	10	5.21	2.46	1.17	5.17	23	10	5.19	2.46	1.17	5.16
PHONOBLOIA	23	10	5.21	2.46	1.17	5.17	23	10	5.19	2.46	1.17	5.16
COMPLICATED APPENDICITIS	15	5	4.68	3.21	1.17	8.83	15	5	4.66	3.20	1.16	8.81
COMPUTERISED TOMOGRAM	15	5	4.68	3.21	1.17	8.83	15	5	4.66	3.20	1.16	8.81
THORAX	36	19	5.80	2.03	1.16	3.53	35	16	7.59	2.34	1.29	4.22
HEARING AID USER	30	15	5.36	2.14	1.15	3.98	30	15	5.32	2.14	1.15	3.97
HEPATIC MASS	27	13	5.15	2.22	1.15	4.31	27	13	5.12	2.22	1.14	4.30
ACUTE CARDIAC EVENT	27	13	5.15	2.22	1.15	4.31	27	13	5.12	2.22	1.14	4.30
CORONARY ANGIOPLASTY	27	13	5.15	2.22	1.15	4.31	27	13	5.12	2.22	1.14	4.30
HYPOSMOLAR STATE	27	13	5.15	2.22	1.15	4.31	27	13	5.12	2.22	1.14	4.30
RED BLOOD CELL	34	18	5.40	2.02	1.14	3.58	30	15	5.32	2.14	1.15	3.97
TRANSFUSION	24	11	4.97	2.33	1.14	4.76	24	11	4.94	2.33	1.14	4.75
LANGUAGE DISORDER	21	9	4.81	2.50	1.14	5.45	22	9	5.47	2.61	1.20	5.67
RENAL MASS	31	16	5.17	2.07	1.13	3.79	30	16	4.58	2.00	1.09	3.67
BRONCHIAL SECRETION												
RETENTION	28	14	4.95	2.14	1.13	4.06	28	14	4.92	2.14	1.12	4.06
DEPERSONALISATION/DIREALI	28	14	4.95	2.14	1.13	4.06	28	14	4.92	2.14	1.12	4.06
SATION DISORDR	28	14	4.95	2.14	1.13	4.06	28	14	4.92	2.14	1.12	4.06
LABOUR INDUCTION	28	14	4.95	2.14	1.13	4.06	28	14	4.92	2.14	1.12	4.06
NIH STROKE SCALE SCORE	28	14	4.95	2.14	1.13	4.06	27	14	4.34	2.06	1.08	3.93
INCREASED	13	4	4.33	3.48	1.13	10.66	13	4	4.31	3.47	1.13	10.64
PHILIP PAIN	32	17	5.00	2.01	1.12	3.63	33	16	6.33	2.20	1.21	4.00
WALKING DISABILITY												
BLOOD CREATINE	25	12	4.75	2.23	1.12	4.44	25	12	4.72	2.22	1.12	4.43
PHOSPHOKINASE INCREASED	25	12	4.75	2.23	1.12	4.44	25	12	4.72	2.22	1.12	4.43
CFRBRAL ARTERY STENOSIS	16	6	4.32	2.85	1.12	7.29	16	6	4.30	2.85	1.11	7.27
APPENDIX DISORDR												
BLOOD POTASSIUM INCREASED	16	6	4.32	2.85	1.12	7.29	16	6	4.30	2.85	1.11	7.27
CIRRHOSIS ALCOHOLIC	16	6	4.32	2.85	1.12	7.29	16	6	4.30	2.85	1.11	7.27
MICROCYTIC ANAEMIA	29	15	4.77	2.07	1.11	3.86	29	15	4.74	2.06	1.11	3.85
THYROID PAIN	22	10	4.56	2.35	1.11	4.97	22	10	4.54	2.35	1.11	4.96

ORTHOSTATIC HYPERTENSION	19	8	4.41	2.54	1.11	5.80	19	8	4.39	2.54	1.11	5.79
INTESTINAL PERFORATION	26	13	4.55	2.14	1.10	4.16	26	13	4.52	2.14	1.10	4.15
TOOTH EXTRACTION	26	13	4.55	2.14	1.10	4.16	26	13	4.52	2.14	1.10	4.15
LABORATORY TEST ABNORMAL	30	16	4.61	2.01	1.09	3.68	29	15	4.74	2.06	1.11	3.85
ALCOHOL WITHDRAWAL SYNDROME	23	11	4.34	2.24	1.09	4.59	23	11	4.32	2.23	1.09	4.58
HIDRADENITIS	23	11	4.34	2.24	1.09	4.59	23	11	4.32	2.23	1.09	4.58
ENDOMETRIOSIS	27	14	4.37	2.06	1.08	3.93	27	14	4.34	2.06	1.08	3.93
ILLUSION	20	9	4.16	2.38	1.08	5.22	20	9	4.14	2.37	1.08	5.21
SOCIAL AVOIDANT BEHAVIOUR	20	9	4.16	2.38	1.08	5.22	20	9	4.14	2.37	1.08	5.21
MITRAL VALVE CALCIFICATION	24	12	4.15	2.14	1.07	4.28	23	11	4.32	2.23	1.09	4.58
SALIVARY GLAND PAIN	18	3	10.31	6.42	1.89	21.79	18	2	12.26	9.61	2.23	41.41
POSTURAL ORTHOSTATIC TACHYCARDIA SYNDROME	144	77	24.44	2.00	1.52	2.64	142	77	23.15	1.97	1.49	2.60
SPINAL DISORDER	34	18	5.40	2.02	1.14	3.58	31	17	4.43	1.95	1.08	3.52
INTRUSIVE THOUGHTS	13	4	4.33	3.48	1.13	10.66	12	4	3.54	3.20	1.03	9.93
PNEUMOPERITONEUM	19	8	4.41	2.54	1.11	5.80	18	8	3.73	2.40	1.04	5.52
IRIDOCYCLITIS	26	13	4.55	2.14	1.10	4.16	25	13	3.95	2.05	1.05	4.01
SPEECH DISORDER DEVELOPMENTAL	23	11	4.34	2.24	1.09	4.59	22	11	3.72	2.14	1.04	4.40
VAGINAL ULCERATION	23	11	4.34	2.24	1.09	4.59	23	12	3.55	2.05	1.02	4.11
CERVICAL RADICULOPATHY	27	14	4.37	2.06	1.08	3.93	25	14	3.26	1.91	0.99	3.67
COMPLICATION OF PREGNANCY	17	7	4.01	2.60	1.08	6.26	17	7	3.99	2.59	1.08	6.25
BODY HEIGHT DECREASED	55	2	51.07	29.42	7.18	120.59	55	2	50.95	29.36	7.16	120.35
PRODUCT LOT NUMBER ISSUE	25	1	21.95	26.74	3.62	197.35	25	1	21.90	26.69	3.62	196.95
PNEUMOTHORAX SPONTANEOUS	18	2	12.30	9.63	2.23	41.49	18	2	12.26	9.61	2.23	41.41
ELDERLY LYMPHOCYTE COUNT DECREASED	13	2	7.37	6.95	1.57	30.81	13	2	7.34	6.94	1.57	30.75
OCULAR VASCULAR DISORDER	13	2	7.37	6.95	1.57	30.81	13	2	7.34	6.94	1.57	30.75
CEREBROSPINAL FLUID LEAKAGE	11	1	7.38	11.77	1.52	91.13	11	1	7.36	11.74	1.52	90.95
CYST RUPTURE	12	2	6.41	6.42	1.44	28.67	12	2	6.40	6.41	1.43	28.62
HYPOAESTHESIA TEETH	12	2	6.41	6.42	1.44	28.67	12	2	6.40	6.41	1.43	28.62
INTERVERTEBRAL DISCITIS	12	2	6.41	6.42	1.44	28.67	12	2	6.40	6.41	1.43	28.62
MENORRHAGIA	12	2	6.41	6.42	1.44	28.67	12	2	6.40	6.41	1.43	28.62
ALOPECIA UNIVERSALIS	10	1	6.38	10.70	1.37	83.56	10	1	6.36	10.68	1.37	83.39
ENTEROBACTER INFECTION	10	1	6.38	10.70	1.37	83.56	10	1	6.36	10.68	1.37	83.39
THERAPEUTIC RESPONSE SHORTENED	10	1	6.38	10.70	1.37	83.56	10	1	6.36	10.68	1.37	83.39
ACUTE STRESS DISORDER	11	2	5.48	5.88	1.30	26.54	11	2	5.47	5.87	1.30	26.49
MUTISM	11	2	5.48	5.88	1.30	26.54	11	2	5.47	5.87	1.30	26.49
CHRONIC PIGMENTED PURPURA	9	1	5.39	9.63	1.22	75.98	9	1	5.37	9.61	1.22	75.83
GASTRITIS EROSIVE	9	1	5.39	9.63	1.22	75.98	9	1	5.37	9.61	1.22	75.83
SCIATIC NERVE INJURY	9	1	5.39	9.63	1.22	75.98	9	1	5.37	9.61	1.22	75.83
BLOOD MAGNESIUM DECREASED	10	2	4.57	5.35	1.17	24.41	10	2	4.56	5.34	1.17	24.36
ECHOCARDIOGRAM ABNORMAL	10	2	4.57	5.35	1.17	24.41	10	2	4.56	5.34	1.17	24.36
LOW DENSITY LIPOPROTEIN INCREASED	10	2	4.57	5.35	1.17	24.41	10	2	4.56	5.34	1.17	24.36
PERICARDIAL DISEASE	10	2	4.57	5.35	1.17	24.41	10	2	4.56	5.34	1.17	24.36
ANGLE CLOSURE GLAUCOMA	8	1	4.42	8.56	1.07	68.42	8	1	4.41	8.54	1.07	68.28
NEOPLASM PROGRESSION	8	1	4.42	8.56	1.07	68.42	8	1	4.41	8.54	1.07	68.28

PREFERRED Medical Dictionary for Regulatory Activities (MedDRA) Terms (VAERS-1 Box 7, VAERS 2.0 Box 18)

For Current Week and Past Week Comparison

Following ALL 12/14/2020-04/29/2022 COVID19 Pfizer Ages 18+ Vaccines

Compared to ALL 12/14/2020-04/29/2022 COVID19 Moderna Ages 18+ Vaccines

SERIOUS AGES 18+ YEARS, Initial domestic reports only, VAERS reports as of 04/29/2022

Vaccination, Received, and Completed Date: 12/14 - 04/29 (Current Week) and 12/14 - 04/22 (Past Week)

N>=3 (Current Week), PRR=2.00 (Ratio of Proportions), Chi-Square=4.00

MedDRA PTs sorting based on lower confidence limit and PFIZER adverse event count from 12/14/2020-04/29/2022

SERIOUS AGES 18+ YEARS excludes missing ages

MedDRA Codes ALL Reports (SERIOUS 18+)	12/14/2020- 04/29/2022 PFIZER N=37523	12/14/2020- 04/29/2022 MODERNA N=30526	12/14-04/29 Chi-Square	12/14-04/29 PRR	12/14-04/29 LCL	12/14-04/29 UCL	12/14/2020- 04/22/2022 PFIZER N=37058	12/14/2020- 04/22/2022 MODERNA N=30309	12/14-04/22 Chi-Square	12/14-04/22 PRR	12/14-04/22 LCL	12/14-04/22 UCL
IMMUNISATION	133	8	86.67	13.60	6.66	27.75	133	8	86.67	13.60	6.66	27.75
APPARENT LIFE THREATENING EVENT	61	7	31.72	7.13	3.26	15.58	61	7	31.72	7.13	3.26	15.58
VACCINATION FAILURE	67	9	32.45	6.09	3.24	12.21	67	9	32.45	6.09	3.04	12.21
DRUG INEFFECTIVE	110	25	37.24	3.60	2.33	5.55	110	25	37.24	3.60	2.33	5.55
WHITE BLOOD CELL COUNT INCREASED	46	8	18.68	4.70	2.22	9.96	46	8	18.68	4.70	2.22	9.96
DISEASE RECURRENCE	33	5	14.31	5.40	2.11	13.83	33	5	14.31	5.40	2.11	13.83
VIBRATORY SENSE INCREASED	25	3	11.95	6.82	2.06	22.57	25	3	11.95	6.82	2.06	22.57
OFF LABEL USE	75	21	19.83	2.92	1.80	4.74	75	21	19.83	2.92	1.80	4.74
EATING DISORDER	44	12	11.64	3.00	1.58	5.68	44	12	11.64	3.00	1.58	5.68
NEAR DEATH EXPERIENCE	49	16	10.11	2.50	1.42	4.40	48	16	9.55	2.45	1.39	4.32
PERTONITIS	32	9	7.89	2.91	1.39	6.09	31	9	7.30	2.82	1.34	5.92
OSTEOPENIA	27	7	7.23	3.15	1.37	7.24	27	7	7.23	3.15	1.37	7.24
VERTEBRAL ARTERY DISSECTION	17	3	6.11	4.63	1.36	15.81	17	3	6.11	4.63	1.36	15.81
BLOOD CHOLESTEROL INCREASED	24	6	6.60	3.27	1.34	8.00	24	6	6.60	3.27	1.34	8.00
NORMAL LABOUR	44	16	7.42	2.25	1.27	3.99	44	16	7.42	2.25	1.27	3.99
PHOTOSENSITIVITY REACTION	26	8	5.49	2.66	1.20	5.87	25	8	4.93	2.56	1.15	5.67
COLOSTOMY	15	3	4.75	4.09	1.18	14.12	14	3	4.09	3.82	1.10	13.28
PNEUMONIA PSEUDOMONAL	15	3	4.75	4.09	1.18	14.12	15	3	4.75	4.09	1.18	14.12
ENDOTRACHEAL INTUBATION COMPLICATION	17	4	4.71	3.48	1.17	10.33	17	4	4.71	3.48	1.17	10.33
VOCAL CORD PARALYSIS	17	4	4.71	3.48	1.17	10.33	17	4	4.71	3.48	1.17	10.33
MAST CELL ACTIVATION SYNDROME	19	5	4.73	3.11	1.16	8.32	19	5	4.73	3.11	1.16	8.32
SYMPTOM RECURRENCE	26	9	4.51	2.36	1.11	5.04	26	9	4.51	2.36	1.11	5.04
BLOOD DISORDER	24	8	4.39	2.45	1.10	5.46	24	8	4.39	2.45	1.10	5.46
RENAL TRANSPLANT	22	7	4.29	2.57	1.10	6.02	21	6	4.77	2.86	1.16	7.09
SALIVARY HYPERSCRETION	22	7	4.29	2.57	1.10	6.02	22	7	4.29	2.57	1.10	6.02
COMPLICATION OF PREGNANCY MATERNAL EXPOSURE BEFORE PREGNANCY	14	3	4.09	3.82	1.10	13.28	14	3	4.09	3.82	1.10	13.28
DECREASED NASAL ABIAL FOLD	33	13	4.55	2.08	1.09	3.94	32	13	4.09	2.01	1.06	3.84
DECREASED NASAL ABIAL FOLD	20	6	4.20	2.73	1.09	6.79	20	6	4.20	2.73	1.09	6.79
BASAL GANGLIA INFARCTION	27	10	4.13	2.21	1.07	4.56	27	10	4.13	2.21	1.07	4.56
BREAST CANCER FEMALE	32	13	4.09	2.01	1.06	3.84	32	13	4.09	2.01	1.06	3.84
MUSCLE FATIGUE	32	13	4.09	2.01	1.06	3.84	33	13	4.55	2.08	1.09	3.94
HAEMOGLOBIN DECREASED	35	14	4.70	2.04	1.10	3.80	34	14	4.24	1.99	1.07	3.70
ESCHERICHIA URINARY TRACT INFECTION	20	6	4.20	2.73	1.09	6.79	18	6	3.11	2.45	0.97	6.18
VASODILATION	18	5	4.13	2.94	1.09	7.93	17	5	3.55	2.78	1.03	7.54

PREFERRED Medical Dictionary for Regulatory Activities (MedDRA) Terms (VAERS-1 Box 7, VAERS 2.0 Box 18)

For Current Week and Past Week Comparison

Following ALL 12/14/2020-04/29/2022 COVID19 Pfizer Ages 18+ Vaccines

Compared to ALL 12/14/2020-04/29/2022 COVID19 Moderna Ages 18+ Vaccines

NON-SERIOUS AGES 18+ YEARS; Initial domestic reports only, VAERS reports as of 04/29/2022

Vaccination, Received, and Completed Date: 12/14 - 04/29 (Current Week) and 12/14 - 04/22 (Past Week)

N>=3 (Current Week), PRR=2.00 (Ratio of Proportions), Chi-Square=4.00

MedDRA PT's sorting based on lower confidence limit and PFIZER adverse event count from 12/14/2020-04/29/2022

NON-SERIOUS AGES 18+ YEARS excludes missing ages

MedDRA Codes ALL Reports (NON-SERIOUS 18+)	12/14/2020- 04/29/2022 PFIZER N=267548	12/14/2020- 04/29/2022 MODERNA N=295577	12/14-04/29 Chi-Square	12/14-04/29 PRR	12/14-04/29 LCL	12/14-04/29 UCL	12/14/2020- 04/22/2022 PFIZER N=266939	12/14/2020- 04/22/2022 MODERNA N=294209	12/14-04/22 Chi-Square	12/14-04/22 PRR	12/14-04/22 LCL	12/14-04/22 UCL
PRODUCT PREPARATION ERROR	558	16	567.16	38.53	23.44	63.33	557	15	567.53	40.93	24.51	68.35
VACCINATION FAILURE	958	50	912.80	21.17	15.93	28.13	939	51	886.92	20.29	15.31	26.90
DISEASE RECURRENCE	184	6	183.50	33.88	15.03	76.39	183	6	181.94	33.62	14.91	75.80
PRODUCT PREPARATION ISSUE	2102	166	1861.23	13.99	11.95	16.38	2099	166	1852.92	13.94	11.90	16.32
PRODUCT USE ISSUE	420	27	385.16	17.19	11.65	25.56	409	27	372.17	16.70	11.31	24.64
IMMUNISATION	2392	207	2073.80	12.77	11.08	14.71	2390	207	2065.94	12.73	11.04	14.67
IMMUNODEFICIENCY	413	65	288.59	7.02	5.40	9.12	412	64	288.74	7.10	5.45	9.23
OFF LABEL USE	925	190	564.49	5.40	4.62	6.31	911	190	545.78	5.28	4.52	6.18
CIRCUMSTANCE OR INFORMATION CAPABLE OF LEADING TO MEDICATION ERROR	118	19	80.42	6.86	4.23	11.14	118	19	80.16	6.84	4.22	11.11
DRUG INEFFECTIVE	976	251	504.66	4.30	3.74	4.93	951	247	485.87	4.24	3.69	4.88
MIDDLE INSOMNIA	75	15	44.89	5.52	3.17	9.62	74	15	43.76	5.44	3.12	9.57
INCORRECT PRODUCT FORMULATION ADMINISTERED	543	160	248.27	3.75	3.14	4.47	545	162	246.09	3.71	3.11	4.42
OVERDOSE	151	48	63.11	3.48	2.51	4.81	152	46	66.54	3.64	2.62	5.06
INTERCHANGE OF VACCINE PRODUCTS	5725	2588	1542.34	2.44	2.33	2.56	5730	2592	1543.43	2.45	2.34	2.56
CROHN'S DISEASE	96	33	36.39	3.21	2.16	4.77	94	33	34.67	3.14	2.11	4.67
NEAR DEATH EXPERIENCE	60	19	24.49	3.49	2.08	5.84	60	19	24.39	3.48	2.08	5.83
SKIN DISORDER	2411	103	69.27	2.58	2.05	3.26	237	102	66.99	2.56	2.03	3.23
DRUG HYPERSENSITIVITY	150	60	47.23	2.76	2.05	3.73	149	59	47.35	2.78	2.06	3.76
EAR DISORDER	97	36	33.46	2.98	2.03	4.36	96	35	33.71	3.02	2.05	4.45
ASYMPTOMATIC COVID-19	334	151	87.91	2.44	2.02	2.96	334	151	87.41	2.44	2.01	2.95
UTERINE HAEMORRHAGE	56	18	22.43	3.44	2.02	5.85	56	18	22.33	3.43	2.02	5.83
POLYMERORRHOEA	448	209	111.94	2.37	2.01	2.79	447	209	110.60	2.36	2.00	2.78
EXPOSURE TO SARS-COV-2	810	399	183.70	2.24	1.99	2.53	801	386	188.28	2.29	2.03	2.58
MENSTRUAL DISORDER	1553	807	317.30	2.13	1.95	2.31	1551	806	314.79	2.12	1.95	2.31
STRIDOR	76	28	26.25	3.00	1.94	4.62	75	28	25.32	2.95	1.91	4.56
INTERMENSTRUAL BLEEDING	855	439	178.46	2.15	1.92	2.41	852	437	177.07	2.15	1.92	2.41
HYPOMENORRHOEA	114	47	34.12	2.68	1.91	3.76	114	47	33.94	2.67	1.90	3.75
UPPER RESPIRATORY TRACT CONGESTION	93	37	29.15	2.78	1.90	4.06	93	36	30.14	2.85	1.94	4.18
SUSPECTED COVID-19	274	130	66.06	2.33	1.89	2.87	264	128	60.72	2.27	1.84	2.81
ANTINUCLEAR ANTIBODY POSITIVE	20	4	10.96	5.52	1.89	16.16	20	4	10.92	5.51	1.88	16.12
MENSTRUATION IRREGULAR	2029	1109	371.38	2.02	1.88	2.17	2015	1106	362.66	2.01	1.87	2.16
DYSMENORRHOEA	1141	612	217.15	2.06	1.87	2.27	1137	616	210.08	2.03	1.84	2.24
FIBRIN D DIMER INCREASED	52	18	19.07	3.19	1.87	5.45	52	18	18.98	3.18	1.86	5.44
NERVE COMPRESSION	125	54	34.88	2.56	1.86	3.52	125	52	36.80	2.65	1.92	3.66
ELECTROCARDIOGRAM ABNORMAL	40	13	15.51	3.40	1.82	6.36	40	13	15.44	3.39	1.81	6.34

RED BLOOD CELL COUNT	24	6	11.43	4.42	1.81	10.81	23	6	10.48	4.22	1.72	10.38
DECREASED												
REFUSAL OF TREATMENT BY	75	31	22.05	2.67	1.76	4.06	75	31	21.93	2.67	1.75	4.05
PATIENT												
BLOOD THYROID STIMULATING	28	8	12.04	3.87	1.76	8.48	27	8	11.12	3.72	1.69	8.19
HORMONE INCREASED												
ANTIALLERGIC THERAPY	16	3	8.84	5.89	1.72	20.22	16	3	8.81	5.88	1.71	20.17
SUPPRESSED LACTATION	89	41	22.05	2.40	1.66	2.47	89	41	21.92	2.39	1.65	3.46
ANKYLOSING SPONDYLITIS	26	8	10.30	3.59	1.63	7.93	25	8	9.41	3.44	1.55	7.64
RED BLOOD CELL												
SEDIMENTATION RATE	28	9	10.67	3.44	1.62	7.28	28	9	10.62	3.43	1.62	7.27
INCREASED												
GASTRIC DISORDER	88	42	20.43	2.31	1.60	3.34	88	41	21.23	2.37	1.63	3.43
WHITE BLOOD CELL COUNT												
INCREASED	67	30	17.23	2.47	1.60	3.79	67	39	18.13	2.45	1.65	3.94
MEASLES	15	3	7.88	5.52	1.60	19.08	15	3	7.85	5.51	1.60	19.04
PHARYNGEAL MASS	15	3	7.88	5.52	1.60	19.08	15	3	7.85	5.51	1.60	19.04
WRIGHT FLUCTUATION	15	3	7.88	5.52	1.60	19.08	15	3	7.85	5.51	1.60	19.04
VAGINAL DISCHARGE	85	41	19.32	2.29	1.58	3.32	84	41	18.54	2.26	1.55	3.28
JAW DISORDER	68	31	16.96	2.42	1.58	3.71	68	31	16.87	2.42	1.58	3.70
LACTATION DISORDER	33	12	11.02	3.04	1.57	5.88	33	12	10.97	3.03	1.57	5.87
VACCINATION SITE												
HYPOAESTHESIA	44	18	12.76	2.76	1.56	4.67	44	18	12.69	2.69	1.56	4.66
DIAGNOSIS	61	28	14.95	2.41	1.54	3.76	58	28	12.83	2.28	1.45	3.58
MOOD ALTERED	104	54	20.52	2.13	1.53	2.96	104	53	21.21	2.16	1.55	3.01
BODY TEMPERATURE												
ABNORMAL	105	55	20.34	2.11	1.52	2.92	105	54	21.01	2.14	1.54	2.98
ROAD TRAFFIC ACCIDENT	58	27	13.82	2.37	1.50	3.75	57	27	13.06	2.33	1.47	3.68
HAFMOGLOBIN DECREASED	37	15	10.73	2.73	1.50	4.96	37	15	10.67	2.72	1.49	4.95
UTERINE SPASM	79	40	16.26	2.18	1.49	3.19	79	40	16.15	2.18	1.49	3.18
BASEDOW'S DISEASE	59	28	13.58	2.33	1.48	3.65	57	27	13.06	2.33	1.47	3.68
BONE DISORDR	33	13	9.88	2.80	1.48	5.33	32	12	10.18	2.94	1.51	5.71
WALKING DISABILITY	22	7	8.24	3.47	1.48	8.13	22	7	8.21	3.46	1.48	8.11
BLOOD BILIRUBIN INCREASED	14	3	6.94	5.16	1.48	17.94	14	3	6.91	5.14	1.48	17.90
SLEEP DISORDER DUE TO A												
GENERAL MEDICAL CONDITION	14	3	6.94	5.16	1.48	17.94	13	3	5.99	4.78	1.36	16.76
OVARIAN CYST	71	36	14.49	2.18	1.46	3.25	69	36	13.14	2.11	1.41	3.16
WHITE BLOOD CELL COUNT												
DECREASED	48	22	11.62	2.41	1.46	3.99	48	22	11.55	2.40	1.45	3.98
C-REACTIVE PROTEIN												
INCREASED	38	16	10.42	2.62	1.46	4.71	38	16	10.36	2.62	1.46	4.69
NASAL PRURITUS	56	27	12.47	2.29	1.45	3.63	57	28	12.18	2.24	1.43	3.53
PSORIATIC ARTHROPATHY	54	26	12.03	2.39	1.44	3.66	54	26	11.96	2.29	1.43	3.65
WRONG PATIENT	32	13	9.13	2.72	1.43	5.18	32	13	9.08	2.71	1.42	5.17
FRUSTRATION TOLERANCE												
DECREASED	69	36	13.23	2.12	1.42	3.17	67	35	12.71	2.11	1.40	3.18
EYE ODIDMA	23	8	7.81	3.18	1.42	7.10	23	8	7.78	3.17	1.42	7.08
FACIAL SPASM	56	28	11.60	2.21	1.40	3.48	57	27	13.06	2.43	1.47	3.68
APRAXIA	19	6	7.03	3.50	1.40	8.76	19	6	7.00	3.49	1.39	8.74
CLAUSTROPHOBIA	17	5	6.67	3.76	1.39	10.18	17	5	6.64	3.75	1.38	10.16
SPECTUM DISCOLOURED	69	37	12.45	2.06	1.38	3.07	68	36	12.53	2.08	1.39	3.12
MASTITIS	63	33	11.92	2.11	1.38	3.21	62	32	12.65	2.17	1.42	3.32
PETIT MAL EPILEPSY	24	9	7.43	2.95	1.37	6.34	24	9	7.40	2.94	1.37	6.32
INCREASED APPETITE	54	28	10.34	2.13	1.35	3.36	54	28	10.27	2.13	1.35	3.36
ABNORMAL UTERINE BLEEDING	40	19	8.94	2.33	1.35	4.02	39	19	8.23	2.26	1.31	3.91
PHARYNGITIS STRIPTOCOCCAL	52	27	9.90	2.13	1.34	3.39	52	26	10.65	2.20	1.38	3.53
MAST CELL ACTIVATION												
SYNDROME	30	13	7.67	2.55	1.33	4.89	30	13	7.63	2.54	1.33	4.88

VIBRATORY SENSE INCREASED	44	22	8.96	2.21	1.32	3.69	41	22	7.06	2.05	1.22	3.45
VASCULAR PAIN	60	33	10.11	2.01	1.31	3.07	60	33	10.04	2.00	1.31	3.06
THYROIDITIS	45	23	8.77	2.16	1.31	3.57	44	23	8.09	2.11	1.37	3.49
HYPORESPONSIVE TO STIMULI	23	9	6.67	2.82	1.31	6.10	23	9	6.64	2.82	1.30	6.09
SUBMAXILLARY GLAND ENLARGEMENT	23	9	6.67	2.82	1.31	6.10	23	9	6.64	2.82	1.30	6.09
HORMONE LEVEL ABNORMAL	55	30	9.40	2.03	1.30	3.16	55	29	10.09	2.09	1.33	3.28
DEFMELINATION	16	5	5.82	3.54	1.30	9.65	16	5	5.80	3.53	1.29	9.63
PHARYNGEAL DISORDER	16	5	5.82	3.54	1.30	9.65	16	5	5.80	3.53	1.29	9.63
PLATELET COUNT INCREASED	26	11	6.80	2.61	1.29	5.28	26	11	6.76	2.61	1.29	5.27
ATELECTASIS	50	27	8.69	2.05	1.28	3.27	50	27	8.63	2.04	1.28	3.26
LIVER DISORDER	33	16	6.96	2.38	1.25	4.14	31	16	5.66	2.14	1.17	3.90
RETINAL VEIN OCCLUSION	33	16	6.96	2.38	1.25	4.14	33	16	6.91	2.27	1.25	4.13
CEREBRAL INFARCTION	12	3	5.11	4.42	1.25	15.66	12	3	5.09	4.41	1.24	15.62
GLUTEN SENSITIVITY	12	3	5.11	4.42	1.25	15.66	11	3	4.22	4.04	1.13	14.49
SICK RELATIVE	12	3	5.11	4.42	1.25	15.66	12	3	5.09	4.41	1.24	15.62
BREAST ENLARGEMENT	43	23	7.54	2.07	1.24	3.43	43	23	7.49	2.06	1.24	3.42
ACUTE KIDNEY INJURY	44	24	7.39	2.03	1.23	3.33	44	24	7.33	2.02	1.23	3.32
ACUTE RESPIRATORY FAILURE	17	6	5.41	3.13	1.23	7.94	17	6	5.39	3.12	1.23	7.92
UTERINE PAIN	35	18	6.57	2.15	1.22	3.79	35	18	6.53	2.14	1.21	3.78
POST-TRAUMATIC STRESS DISORDER	20	8	5.50	2.76	1.22	6.37	20	8	5.47	2.76	1.21	6.26
MENTAL FATIGUE	42	23	6.96	2.02	1.21	3.35	42	23	6.90	2.01	1.21	3.35
EPICONDYLITIS	26	12	5.85	2.39	1.21	4.74	26	12	5.81	2.39	1.20	4.73
INCORRECT PRODUCT ADMINISTRATION DURATION	23	10	5.65	2.54	1.21	5.34	23	10	5.62	2.53	1.21	5.33
POLYURIA	36	19	6.40	2.09	1.20	3.65	36	19	6.36	2.09	1.20	3.64
BLADDER DISORDER	33	17	6.13	2.14	1.19	3.85	33	17	6.09	2.14	1.19	3.84
TIC	33	17	6.13	2.14	1.19	3.85	33	17	6.09	2.14	1.19	3.84
LABORATORY TEST ABNORMAL	18	7	5.07	2.84	1.19	6.80	18	7	5.04	2.83	1.18	6.79
TOOTH DISORDER	34	18	5.96	2.09	1.18	3.69	33	18	5.34	2.02	1.14	3.59
PHARYNGEAL ULCERATION	21	9	5.22	2.58	1.18	5.63	21	9	5.19	2.57	1.18	5.61
BLOOD POTASSIUM INCREASED	13	4	4.61	3.59	1.17	11.01	13	4	4.59	3.58	1.17	10.99
NEUTROPHIL COUNT DECREASED	13	4	4.61	3.59	1.17	11.01	13	4	4.59	3.58	1.17	10.99
VISUAL ACUTY REDUCED	28	14	5.44	2.21	1.16	4.20	28	14	5.40	2.20	1.16	4.19
IRIDOCYLITIS	22	10	4.97	2.43	1.15	5.13	21	10	4.28	2.31	1.09	4.91
TONGUE MOVEMENT DISTURBANCE	22	10	4.97	2.43	1.15	5.13	22	10	4.94	2.42	1.15	5.12
BREAST INDURATION	19	8	4.78	2.62	1.15	5.99	19	8	4.75	2.62	1.15	5.98
ENDOMETRIAL THICKENING	19	8	4.78	2.62	1.15	5.99	19	8	4.75	2.62	1.15	5.98
ILLUSION	16	6	4.64	2.95	1.15	7.53	16	6	4.62	2.94	1.15	7.51
TOOTH EXTRACTION	16	6	4.64	2.95	1.15	7.53	16	6	4.62	2.94	1.15	7.51
ALANINE AMINOTRANSFERASE INCREASED	33	18	5.38	2.03	1.14	3.60	33	18	5.34	2.02	1.14	3.59
POLYARTHRTIS	30	16	5.10	2.07	1.13	3.80	31	16	5.66	2.14	1.17	3.90
PAROTID GLAND ENLARGEMENT	23	11	4.75	2.31	1.13	4.74	23	11	4.72	2.30	1.12	4.73
LABILE BLOOD PRESSURE	11	3	4.24	4.05	1.13	14.52	11	3	4.22	4.04	1.13	14.49
SPECTUM INCREASED	11	3	4.24	4.05	1.13	14.52	11	3	4.22	4.04	1.13	14.49
THERAPEUTIC PRODUCT EFFECT DECREASED	11	3	4.24	4.05	1.13	14.52	11	3	4.22	4.04	1.13	14.49
SIODREN'S SYNDROME	31	17	4.95	2.01	1.12	3.64	31	17	4.91	2.01	1.11	3.63
INTRACRANIAL PRESSURE INCREASED	20	9	4.53	2.46	1.12	5.39	20	9	4.50	2.45	1.12	5.38

ATTENTION DEFICIT	17	7	4.34	2.68	1.11	6.47	17	6	5.39	3.12	1.23	792
HYPERACTIVITY DISORDER	14	5	4.22	3.09	1.11	8.59	14	5	4.20	3.09	1.11	857
ANAL HAEMORRHAIGE	14	5	4.22	3.09	1.11	8.59	14	5	4.20	3.09	1.11	857
IMMUNISATION ANXIETY	14	5	4.22	3.09	1.11	8.59	14	5	4.20	3.09	1.11	857
RELATED REACTION	14	5	4.22	3.09	1.11	8.59	14	5	4.20	3.09	1.11	857
PATIENT ISOLATION	21	10	4.31	2.32	1.09	4.93	21	10	4.28	2.31	1.09	491
THYROID PAIN	26	14	4.23	2.05	1.07	2.36	26	14	3.95	2.05	1.07	392
MUSCLE INJURY	17	3	9.82	6.26	1.83	21.36	17	2	11.75	9.37	2.16	4055
SALIVARY GLAND PAIN	2630	1443	478.14	2.01	1.89	2.15	2614	1442	465.93	2.00	1.87	2.13
HEAVY MENSTRUAL BLEEDING	39	21	6.67	2.05	1.21	3.49	39	22	5.91	1.95	1.16	3.29
FACIAL ASYMMETRY	11	3	4.24	14.52	1.13	3.39	10	3	5.39	3.67	1.01	13.35
SCROTAL PAIN	17	7	4.34	2.68	1.11	6.47	15	7	2.97	2.36	0.96	5.79
CERVICAL RADICULOPATHY	21	10	4.31	2.32	1.09	4.93	21	11	3.49	2.10	1.01	4.36
VAGINAL ULTRATATION	50	1	50.21	55.24	7.63	399.86	50	1	50.09	55.11	7.61	398.92
BODY HEIGHT DECREASED	15	2	9.73	8.29	1.89	36.23	15	2	9.70	8.27	1.89	36.15
PRIMARYNGEAL INFLAMMATION	12	1	8.74	13.26	1.72	101.95	12	1	8.72	13.23	1.72	101.71
LYMPHOCYTE COUNT	12	2	6.73	6.63	1.48	29.62	12	2	6.71	6.61	1.48	29.55
VENOUS THROMBOSIS	10	1	6.66	11.05	1.41	86.30	10	1	6.64	11.02	1.41	86.10
HYPOAESTHESIA TEETH	11	2	5.77	6.08	1.35	27.41	11	2	5.75	6.06	1.34	27.35
GESTATIONAL DIABETES	11	2	5.77	6.08	1.35	27.41	10	2	4.80	5.51	1.21	25.15
HYPOMAGNEAEMIA	9	1	5.64	9.94	1.26	78.48	9	1	5.62	9.92	1.26	78.29
INFLAMMATORY MARKER	9	1	5.64	9.94	1.26	78.48	9	1	5.62	9.92	1.26	78.29
INCREASED	9	1	5.64	9.94	1.26	78.48	9	1	5.62	9.92	1.26	78.29
POTENTIATING DRUG	9	1	5.64	9.94	1.26	78.48	9	1	5.62	9.92	1.26	78.29
INTERACTION	9	1	5.64	9.94	1.26	78.48	9	1	5.62	9.92	1.26	78.29
THERAPEUTIC RESPONSE	9	1	5.64	9.94	1.26	78.48	9	1	5.62	9.92	1.26	78.29
SHORTENED	9	1	5.64	9.94	1.26	78.48	9	1	5.62	9.92	1.26	78.29
WOUND DRAINAGE	10	2	4.82	5.52	1.21	25.21	10	2	4.80	5.51	1.21	25.15
BRAIN INJURY	10	2	4.82	5.52	1.21	25.21	10	2	4.80	5.51	1.21	25.15
BRAIN INJURY	10	2	4.82	5.52	1.21	25.21	10	2	4.80	5.51	1.21	25.15
CYST RUPTURE	10	2	4.82	5.52	1.21	25.21	10	2	4.80	5.51	1.21	25.15
ALOPECIA UNIVERSALIS	8	1	4.63	8.84	1.11	70.66	8	1	4.62	8.82	1.10	70.50
CEREBROSPINAL FLUID	8	1	4.63	8.84	1.11	70.66	8	1	4.62	8.82	1.10	70.50
LEAKAGE	8	1	4.63	8.84	1.11	70.66	8	1	4.62	8.82	1.10	70.50
CHRONIC PIGMENTED PURPURA	8	1	4.63	8.84	1.11	70.66	8	1	4.62	8.82	1.10	70.50
SCIATIC NERVE INJURY	8	1	4.63	8.84	1.11	70.66	8	1	4.62	8.82	1.10	70.50
VENTRICULAR ARRHYTHMIA	8	1	4.63	8.84	1.11	70.66	8	1	4.62	8.82	1.10	70.50
RESPIRATORY DISORDER	120	67	20.16	1.98	1.47	2.67	120	66	20.75	2.00	1.48	2.71
NAIL DISCOLOCATION	33	19	8.39	1.98	1.26	3.12	33	29	8.90	2.01	1.28	3.17
INOPASM	33	19	8.39	1.98	1.26	3.12	33	18	8.90	2.01	1.28	3.17
GINGIVAL DISORDER	15	6	3.91	2.76	1.07	7.12	15	5	4.98	3.31	1.20	9.10
OVERSENSING	20	10	3.68	2.21	1.03	4.72	21	10	4.28	2.31	1.09	4.91
CLONUS	10	3	3.41	3.68	1.01	13.38	10	2	4.80	5.51	1.21	25.15
EUSTACHIAN TUBE	7	1	3.65	7.73	0.95	62.85	8	1	4.62	8.82	1.10	70.50
OBSTRUCTION	7	1	3.65	7.73	0.95	62.85	8	1	4.62	8.82	1.10	70.50
BREAST CALCIFICATIONS	5	1	1.82	5.52	0.65	47.28	5	0	-	-	-	-

PREFERRED Medical Dictionary for Regulatory Activities (MedDRA) Terms (VAERS-1 Box 7, VAERS 2.0 Box 18)

For Current Week and Past Week Comparison

Following **ALL 12/14/2020-04/29/2022 COVID19 MODERNA Ages 18+ Vaccines**Compared to **ALL 12/14/2020-04/29/2022 COVID19 PFIZER Ages 18+ Vaccines****AGES 18+ YEARS**, Initial domestic reports only, VAERS reports as of 04/29/2022

Vaccination, Received, and Completed Date: 12/14 - 04/29 (Current Week) and 12/14 - 04/22 (Past Week)

N $\geq$ 3 (Current Week), PRR $\geq$ 2.00 (Ratio of Proportions), Chi-Square $\geq$ 4.00

MedDRA PTs sorting based on lower confidence limit and MODERNA adverse event count from 12/14/2020-04/29/2022

AGES 18+ YEARS excludes missing ages

MedDRA Codes ALL Reports (18+)	12/14/2020- 04/29/2022 MODERNA N=326103	12/14/2020- 04/29/2022 PFIZER N=304871	12/14-04/29 Chi-Square	12/14-04/29 PRR	12/14-04/29 LCL	12/14-04/29 UCL	12/14/2020- 04/22/2022 MODERNA N=324518	12/14/2020- 04/22/2022 PFIZER N=303997	12/14-04/22 Chi-Square	12/14-04/22 PRR	12/14-04/22 LCL	12/14-04/22 UCL
PRODUCT DOSE OMISSION ISSUE	1627	71	1326.38	21.42	16.89	27.17	1627	71	1329.32	21.47	16.93	27.22
MECHANICAL URTICARIA	769	59	561.70	12.19	9.35	15.88	760	59	554.77	12.07	9.26	15.73
ACCIDENTAL OVERDOSE	293	21	216.36	13.04	8.38	20.31	285	21	209.52	12.71	8.16	19.80
VACCINATION SITE INDURATION	1083	103	745.83	9.83	8.03	12.03	1083	103	747.67	9.85	8.05	12.05
INTENTIONAL PRODUCT USE ISSUE	132	9	97.64	13.71	6.98	26.94	132	9	97.87	13.74	6.99	26.99
INJECTION SITE RASH	10222	1398	6240.49	6.84	6.47	7.23	10224	1396	6263.67	6.86	6.49	7.25
INJECTION SITE PRURITUS	18100	2597	10962.72	6.52	6.26	6.79	18112	2592	11015.40	6.55	6.28	6.82
INJECTION SITE INDURATION	5058	735	2970.83	6.43	5.96	6.95	5062	736	2980.62	6.44	5.96	6.96
INJECTION SITE WARMTH	13068	2102	7390.69	5.81	5.55	6.08	13072	2102	7415.94	5.83	5.56	6.10
DEVICE CONNECTION ISSUE	300	42	176.51	6.68	4.84	9.22	301	42	177.87	6.71	4.86	9.27
INJECTION SITE ERYTHEMA	25246	4792	13228.07	4.93	4.78	5.08	25257	4777	13308.00	4.95	4.80	5.11
TYPE IV HYPERSENSITIVITY REACTION	117	13	74.92	8.41	4.74	14.92	117	13	75.12	8.43	4.75	14.95
INTENTIONAL DOSE OMISSION	85	9	54.97	8.83	4.44	17.55	85	9	55.11	8.85	4.45	17.59
PRODUCT LABEL CONFUSION	44	3	31.44	13.71	4.26	44.16	44	3	31.52	13.74	4.27	44.25
VACCINATION SITE PRURITUS	3267	679	1537.75	4.50	4.14	4.89	3265	677	1544.35	4.52	4.16	4.91
VACCINATION SITE WARMTH	2718	560	1286.03	4.54	4.14	4.97	2713	559	1287.66	4.55	4.15	4.98
VACCINATION SITE RASH	2072	434	966.94	4.46	4.03	4.95	2070	435	966.70	4.46	4.02	4.94
VACCINATION SITE REACTION	1049	214	697.58	4.58	3.96	5.31	1049	213	500.83	4.61	3.98	5.35
INJECTION SITE REACTION	4031	889	1815.64	4.24	3.94	4.56	4034	886	1828.93	4.27	3.97	4.59
INJECTION SITE URTICARIA	1269	267	588.82	4.44	3.89	5.07	1272	268	591.48	4.45	3.90	5.07
INJECTION SITE INFLAMMATION	876	184	406.29	4.45	3.80	5.22	871	183	405.16	4.46	3.80	5.23
INJECTION SITE HYPERSENSITIVITY	150	24	81.70	5.84	3.80	8.99	151	24	82.79	5.89	3.83	9.07
EXPIRED PRODUCT ADMINISTERED	13813	3176	5317.50	3.77	3.63	3.92	11817	3060	4714.01	3.62	3.48	3.76
INJECTION SITE SWELLING	19605	4917	8161.94	3.73	3.61	3.84	19603	4902	8213.04	3.75	3.63	3.86
INJECTION SITE PAPULE	53	6	32.88	8.26	3.55	19.21	53	6	32.96	8.27	3.56	19.25
INDURATION	1714	408	720.37	3.93	3.53	4.37	1711	408	720.43	3.93	3.53	4.38
INJECTION SITE IRRITATION	260	53	122.27	4.59	3.41	6.16	261	53	123.47	4.61	3.43	6.20
VACCINATION SITE ERYTHEMA	4878	1273	1896.69	3.58	3.37	3.81	4874	1266	1910.66	3.61	3.39	3.84
VACCINATION SITE LYMPHADENOPATHY	155	29	76.82	5.00	3.36	7.43	155	27	80.63	5.38	3.57	8.09
INJECTION SITE CELLULITIS	331	72	148.53	4.30	3.33	5.55	331	71	150.64	4.37	3.38	5.64
PRODUCT ADMINISTRATION INTERRUPTED	31	3	19.69	9.66	2.95	31.60	31	3	19.74	9.68	2.96	31.66
INJECTION SITE MASS	2307	693	766.61	3.11	2.86	3.39	2306	691	771.50	3.13	2.87	3.40
SKIN WARM	6811	2310	2078.31	2.88	2.75	3.02	6807	2195	2102.67	2.91	2.77	3.05

POOR QUALITY PRODUCT ADMINISTERED	730	214	248.02	3.19	2.74	3.71	712	214	235.88	3.12	2.68	3.63
VACCINATION SITE URTICARIA	253	67	95.03	3.53	2.70	4.62	252	67	94.61	3.52	2.69	4.61
LOCAL REACTION	233	61	88.43	3.57	2.69	4.73	233	59	91.65	3.70	2.78	4.92
INJECTION SITE NODULE	900	276	290.32	3.05	2.66	3.49	898	275	291.31	3.06	2.67	3.50
VACCINATION COMPLICATION	2659	884	778.13	2.81	2.61	3.03	2660	884	782.11	2.82	2.61	3.04
SKIN INDURATION	162	42	61.73	3.61	2.57	5.06	162	42	61.95	3.61	2.57	5.07
SKIN REACTION	552	171	175.37	3.02	2.54	3.58	551	170	176.62	3.04	2.56	3.61
MATERNAL EXPOSURE DURING PREGNANCY	722	232	219.40	2.91	2.51	3.37	720	232	218.91	2.91	2.51	3.37
VACCINATION SITE DISCOLOURATION	258	75	87.75	3.22	2.49	4.16	258	75	88.08	3.22	2.49	4.17
INJECTION SITE OEDEMA	174	48	62.31	3.39	2.46	4.66	175	48	63.29	3.42	2.48	4.70
INJECTION SITE INDENTATION	99	25	38.25	3.70	2.39	5.74	99	25	38.39	3.71	2.39	5.75
VACCINATION SITE MOVEMENT IMPAIRMENT	269	85	82.83	2.96	2.32	3.78	268	82	86.22	3.06	2.39	3.92
VACCINATION SITE SWELLING	3763	1432	902.54	2.46	2.31	2.61	3754	1428	905.28	2.46	2.32	2.62
INJECTION SITE DISCOLOURATION	473	164	129.19	2.70	2.26	3.22	473	162	132.05	2.74	2.29	3.27
VACCINATION SITE DISCHARGE	41	8	18.82	4.79	2.25	10.22	41	8	18.88	4.80	2.25	10.24
CELLULITIS	1181	448	282.56	2.46	2.21	2.75	1186	448	287.08	2.48	2.22	2.76
CHRONIC SPONTANEOUS URTICARIA	117	34	39.24	3.22	2.20	4.71	116	33	39.98	3.29	2.24	4.85
RASH ERYTHEMATOUS	7318	3046	1510.88	2.25	2.15	2.34	7311	3044	1516.53	2.25	2.16	2.35
PRODUCT AVAILABILITY ISSUE	26	4	13.34	6.08	2.12	17.41	26	4	13.38	6.09	2.13	17.45
POST-ACUTE COVID-19 SYNDROME	233	80	64.04	2.72	2.11	3.51	230	75	68.13	2.87	2.21	3.73
EXPOSURE VIA SKIN CONTACT	119	38	35.61	2.93	2.03	4.22	119	38	35.75	2.93	2.04	4.23
ERYTHEMA	15860	7210	2791.70	2.06	2.00	2.11	15843	7187	2818.21	2.07	2.01	2.12
EXPOSURE VIA BREAST MILK	54	14	19.84	3.61	2.00	6.49	54	14	19.92	3.61	2.01	6.50
INJECTION SITE STREAKING	48	12	18.15	3.74	1.99	7.04	48	11	19.70	4.09	2.12	7.87
SKIN SWELLING	491	201	102.36	2.28	1.94	2.69	486	200	100.74	2.28	1.93	2.68
INJECTION SITE INFECTION	106	35	30.24	2.83	1.93	4.15	106	35	30.37	2.84	1.94	4.16
INJECTION SITE ABSCESS	81	25	24.99	3.03	1.93	4.74	81	25	25.09	3.04	1.94	4.75
SKIN INFECTION	67	23	18.92	2.85	1.76	4.61	66	23	17.19	2.69	1.67	4.32
ERYTHEMA MULTIFORME	131	51	29.22	2.40	1.74	3.32	130	51	28.75	2.39	1.73	3.30
ANTIBODY TEST NEGATIVE	24	5	10.01	4.49	1.71	11.76	24	5	10.04	4.50	1.72	11.78
VACCINATION SITE CELLULITIS	46	14	14.02	3.07	1.69	5.59	45	13	14.62	3.24	1.75	6.01
VACCINATION SITE INFLAMMATION	160	67	31.40	2.23	1.68	2.97	160	67	31.57	2.24	1.68	2.98
INJECTION SITE MACULE	22	5	8.45	4.11	1.56	10.86	22	5	8.47	4.12	1.56	10.88
URTICARIA CHRONIC	122	54	21.23	2.11	1.53	2.91	122	53	22.20	2.16	1.56	2.98
INJECTION SITE EXTRAVASATION	92	39	17.31	2.21	1.52	3.21	91	39	16.84	2.19	1.50	3.18
INJECTION SITE PUSTULE	37	12	10.21	2.88	1.50	5.53	37	12	10.25	2.89	1.51	5.54
INJECTION SITE LYMPHADENOPATHY	85	38	14.27	2.09	1.43	3.07	84	38	13.81	2.07	1.41	3.04
TOOTH LOSS	22	6	7.07	3.43	1.39	8.45	22	6	7.09	3.43	1.39	8.47
INJECTION SITE SCAR	38	14	8.69	2.54	1.38	4.68	38	14	8.74	2.54	1.38	4.69
INJECTION SITE SCAB	57	25	9.74	2.13	1.33	3.41	57	25	9.79	2.14	1.33	3.42
VACCINATION SITE SCAR	25	8	6.73	2.92	1.32	6.48	25	8	6.76	2.93	1.32	6.49
MULTIPLE USE OF SINGLE-USE PRODUCT	14	3	5.23	4.36	1.25	15.18	14	3	5.25	4.37	1.26	15.21
DENTAL DISCOMFORT	39	17	6.53	2.14	1.21	3.79	39	17	6.57	2.15	1.22	3.80
LIMB IMMOBILISATION	32	13	6.05	2.30	1.21	4.38	32	13	6.08	2.31	1.21	4.39
MYOSCLEROSIS	37	16	6.27	2.16	1.20	3.89	37	16	6.30	2.17	1.21	3.89

FEELING OF RELAXATION	26	10	5.29	2.43	1.17	5.04	26	10	5.31	2.44	1.17	5.05
PRODUCT COLOUR ISSUE	13	3	4.48	4.05	1.15	14.22	13	3	4.50	4.06	1.16	14.24
GINGIVITIS	22	8	4.80	2.57	1.14	5.77	22	8	4.82	2.58	1.15	5.79
LEFT VENTRICULAR ENLARGEMENT	18	6	4.33	2.80	1.11	7.07	18	6	4.35	2.81	1.12	7.08
ACCIDENTAL UNDERDOSE	206	2	18.96	96.29	23.92	387.61	206	2	183.47	95.55	23.74	384.65
VACCINATION SITE DYS/ANESTHESIA	20	1	14.26	18.70	2.51	139.32	20	1	14.29	18.74	2.51	139.60
PRODUCT CONTAMINATION PHYSICAL	19	1	13.34	17.76	2.38	132.69	19	1	13.38	17.80	2.38	132.95
VACCINATION SITE ANAESTHESIA	19	1	13.34	17.76	2.38	132.69	19	1	13.38	17.80	2.38	132.95
VACCINATION SITE HYPERSENSITIVITY	16	2	8.54	7.48	1.72	32.53	16	2	8.57	7.49	1.72	32.59
PRODUCT EXPIRATION DATE ISSUE	15	2	7.69	7.01	1.60	30.66	15	2	6.04	6.09	1.37	26.98
VACCINATION SITE STREAKING	11	2	4.40	5.14	1.14	23.20	11	2	4.42	5.15	1.14	23.24

PREFERRED Medical Dictionary for Regulatory Activities (MedDRA) Terms (VAERS-1 Box 7, VAERS 2.0 Box 18)

For Current Week and Past Week Comparison

Following **ALL 12/14/2020-04/29/2022 COVID19 MODERNA Ages 18+ Vaccines**

Compared to **ALL 12/14/2020-04/29/2022 COVID19 PFIZER Ages 18+ Vaccines**

SERIOUS AGES 18+ YEARS, Initial domestic reports only, VAERS reports as of 04/29/2022

Vaccination, Received, and Completed Date: 12/14 - 04/29 (Current Week) and 12/14 - 04/22 (Past Week)

N $\geq$ 3 (Current Week), PRR $\geq$ 2.00 (Ratio of Proportions), Chi-Square $\geq$ 4.00

MedDRA PTs sorting based on lower confidence limit and MODERNA adverse event count from 12/14/2020-04/29/2022

SERIOUS AGES 18+ YEARS excludes missing ages

MedDRA Codes ALL Reports (SERIOUS 18+)	12/14/2020- 04/29/2022 MODERNA N=30526	12/14/2020- 04/29/2022 PFIZER N=37323	12/14-04/29 Chi-Square	12/14-04/29 PRR	12/14-04/29 LCL	12/14-04/29 UCL	12/14/2020- 04/22/2022 MODERNA N=30309	12/14/2020- 04/22/2022 PFIZER N=37058	12/14-04/22 Chi-Square	12/14-04/22 PRR	12/14-04/22 LCL	12/14-04/22 UCL
PRODUCT DOSE OMISSION												
ISSUE	127	18	104.81	8.63	5.27	14.13	127	18	104.81	8.63	5.27	14.13
MECHANICAL URTICARIA	22	3	16.99	8.97	2.68	29.95	20	3	14.72	8.15	2.42	27.43
INJECTION SITE ERYTHEMA	138	57	51.47	2.96	2.17	4.03	138	55	53.90	3.07	2.25	4.19
VACCINATION SITE ERYTHEMA	36	12	16.29	3.67	1.91	7.05	35	12	15.34	3.57	1.85	6.87
INJECTION SITE PRURITUS	67	29	22.90	2.82	1.83	4.37	66	29	22.06	2.78	1.80	4.31
INJECTION SITE SWELLING	146	78	36.19	2.29	1.74	3.01	146	77	37.09	2.32	1.76	3.05
INJECTION SITE WARMTH	57	26	17.89	2.68	1.69	4.26	57	26	17.89	2.68	1.69	4.26
INJECTION SITE REACTION	47	22	14.00	2.61	1.57	4.33	46	22	13.22	2.56	1.54	4.25
OPTIC ISCHAEMIC NEUROPATHY	21	7	9.02	3.67	1.56	8.63	20	7	8.09	3.49	1.48	8.26
INCOMPLETE COURSE OF VACCINATION	99	57	20.81	2.12	1.53	2.94	99	56	21.62	2.16	1.56	3.00
DRUG REACTION WITH EOSINOPHILIA AND SYSTEMIC SYMPTOMS	17	5	8.01	4.16	1.53	11.27	17	5	8.01	4.16	1.53	11.27
GRANULOMA	14	4	6.55	4.28	1.41	13.00	14	4	6.55	4.28	1.41	13.00
VACCINATION SITE RASH	14	4	6.55	4.28	1.41	13.00	14	4	6.55	4.28	1.41	13.00
VACCINATION SITE REACTION	14	4	6.55	4.28	1.41	13.00	14	4	6.55	4.28	1.41	13.00
INJECTION SITE INDURATION	27	12	8.31	2.75	1.39	5.43	27	12	8.31	2.75	1.39	5.43
VACCINATION SITE WARMTH	17	6	6.65	3.46	1.37	8.79	17	6	6.65	3.46	1.37	8.79
SUDDEN CARDIAC DEATH	43	25	8.43	2.10	1.28	3.44	42	24	8.54	2.14	1.30	3.53
CHOLECYSTITIS INFECTIVE	16	6	5.77	3.26	1.28	8.33	16	6	5.77	3.26	1.28	8.33
RASH PAPULAR	40	23	7.99	2.13	1.27	3.55	40	23	7.99	2.13	1.27	3.55
CARDIAC DISCOMFORT	22	10	6.37	2.69	1.27	5.68	21	10	5.60	2.57	1.21	5.45
ECTOPIC PREGNANCY	11	3	5.10	4.48	1.25	16.07	11	3	5.10	4.48	1.25	16.07
VENA CAVA THROMBOSIS	11	3	5.10	4.48	1.25	16.07	11	3	5.10	4.48	1.25	16.07
IMPAIRED HEALING	26	14	5.69	2.27	1.19	4.35	25	13	5.83	2.35	1.20	4.60
FACET JOINT SYNDROME	15	6	4.91	3.06	1.19	7.88	15	6	4.91	3.06	1.19	7.88
DISSOCIATION	12	4	4.67	3.67	1.18	11.37	12	4	4.67	3.67	1.18	11.37
LEFT VENTRICULAR ENLARGEMENT	12	4	4.67	3.67	1.18	11.37	12	4	4.67	3.67	1.18	11.37
MYOCARDIAL FIBROSIS	29	17	5.35	2.09	1.15	3.79	28	17	4.73	2.01	1.10	3.68
B-CELL LYMPHOMA	13	5	4.35	3.18	1.13	8.92	13	5	4.35	3.18	1.13	8.92
NERVE BLOCK	10	3	4.14	4.08	1.12	14.81	10	3	4.14	4.08	1.12	14.81
TOBACCO USER	28	17	4.73	2.01	1.10	3.68	28	17	4.73	2.01	1.10	3.68
RIGHT VENTRICULAR FAILURE	25	15	4.28	2.04	1.07	3.86	25	15	4.28	2.04	1.07	3.86
COMPRESSION GARMENT APPLICATION	12	4	4.67	3.67	1.18	11.37	11	4	3.79	3.36	1.07	10.56
FEEDING TUBE USER	28	17	4.73	2.01	1.10	3.68	27	17	4.13	1.94	1.06	3.56
EMBOLISM VENOUS	25	15	4.28	2.04	1.07	3.86	24	15	3.67	1.96	1.03	3.73
SLEEP DEFICIT	13	2	8.91	7.95	1.79	35.21	13	2	8.91	7.95	1.79	35.21

PREFERRED Medical Dictionary for Regulatory Activities (MedDRA) Terms (VAERS-1 Box 7, VAERS 2.0 Box 18)

For Current Week and Past Week Comparison

Following **ALL 12/14/2020-04/29/2022 COVID19 MODERNA Ages 18+ Vaccines**Compared to **ALL 12/14/2020-04/29/2022 COVID19 PFIZER Ages 18+ Vaccines****NON-SERIOUS AGES 18+ YEARS**, Initial domestic reports only, VAERS reports as of 04/29/2022

Vaccination, Received, and Completed Date: 12/14 - 04/29 (Current Week) and 12/14 - 04/22 (Past Week)

N $\geq$ 3 (Current Week), PRR $\geq$ 2.00 (Ratio of Proportions), Chi-Square $\geq$ 4.00

MedDRA PTs sorting based on lower confidence limit and MODERNA adverse event count from 12/14/2020-04/29/2022

NON-SERIOUS AGES 18+ YEARS excludes missing ages

MedDRA Codes ALL Reports (NON-SERIOUS 18+)	12/14/2020- 04/29/2022 MODERNA N=295577	12/14/2020- 04/29/2022 PFIZER N=267548	12/14-04/29 Chi-Square	12/14-04/29 PRR	12/14-04/29 LCL	12/14-04/29 UCL	12/14/2020- 04/22/2022 MODERNA N=294209	12/14/2020- 04/22/2022 PFIZER N=266939	12/14-04/22 Chi-Square	12/14-04/22 PRR	12/14-04/22 LCL	12/14-04/22 UCL
PRODUCT DOSE OMISSION												
ISSUE	1500	53	1212.61	25.62	19.48	33.69	1500	53	1215.73	25.68	19.53	33.77
ACCIDENTAL OVERDOSE	286	13	221.77	19.91	11.42	34.72	278	13	215.15	19.40	11.13	33.84
MECHANICAL URTICARIA	747	56	528.26	12.07	9.20	15.84	740	56	523.52	11.99	9.14	15.73
VACCINATION SITE												
INDURATION	1071	101	710.84	9.60	7.83	11.77	1071	101	712.92	9.62	7.85	11.80
INJECTION SITE RASH	10171	1363	6014.39	6.75	6.38	7.15	10173	1361	6039.84	6.78	6.41	7.17
INTENTIONAL PRODUCT USE												
ISSUE	124	9	86.93	12.47	6.34	24.53	124	9	87.17	12.50	6.35	24.59
INJECTION SITE PRURITUS	18033	2568	10529.93	6.36	6.10	6.62	18046	2563	10587.31	6.39	6.13	6.66
INJECTION SITE INDURATION	5031	723	2845.44	6.30	5.83	6.81	5035	724	2856.26	6.31	5.84	6.82
INJECTION SITE WARMTH	13011	2076	7079.87	5.67	5.42	5.94	13015	2076	7107.92	5.69	5.43	5.96
TYPE IV HYPERSENSITIVITY												
REACTION	116	11	75.33	9.55	5.14	17.71	116	11	75.55	9.57	5.16	17.76
DEVICE CONNECTION ISSUE	299	41	170.04	6.60	4.76	9.15	300	41	171.44	6.64	4.79	9.20
INJECTION SITE ERYTHEMA	25108	4735	12652.90	4.80	4.66	4.95	25119	4722	12734.22	4.83	4.68	4.98
INTENTIONAL DOSE OMISSION	74	7	47.53	9.57	4.41	20.77	74	7	47.67	9.59	4.42	20.82
PRODUCT LABEL CONFUSION	44	3	30.25	13.28	4.12	42.75	44	3	30.34	13.31	4.13	42.85
VACCINATION SITE WARMTH	2701	554	1219.33	4.41	4.03	4.83	2696	553	1221.60	4.42	4.04	4.85
VACCINATION SITE PRURITUS	3255	674	1460.86	4.37	4.02	4.75	3254	672	1468.92	4.39	4.04	4.77
VACCINATION SITE RASH	2058	430	914.45	4.33	3.91	4.81	2056	431	914.70	4.33	3.90	4.80
INJECTION SITE URTICARIA	1256	355	568.94	4.46	3.90	5.10	1259	356	571.79	4.46	3.90	5.10
INJECTION SITE REACTION	3984	867	1722.43	4.16	3.87	4.48	3988	864	1737.14	4.19	3.89	4.51
VACCINATION SITE REACTION	1035	210	468.61	4.46	3.85	5.17	1035	209	472.04	4.49	3.87	5.21
INJECTION SITE												
HYPERSENSITIVITY	148	23	78.22	5.82	3.75	9.04	149	23	79.31	5.88	3.79	9.12
INJECTION SITE												
INFLAMMATION	869	181	385.38	4.35	3.70	5.10	864	180	384.53	4.36	3.71	5.11
INDURATION	1685	383	698.37	3.98	3.56	4.45	1683	383	699.59	3.99	3.57	4.45
INJECTION SITE SWELLING	19459	4839	7753.42	3.64	3.53	3.75	19457	4825	7806.59	3.66	3.55	3.77
EXPIRED PRODUCT												
ADMINISTERED	12806	3174	5040.53	3.65	3.51	3.80	11810	3058	4463.76	3.50	3.37	3.64
INJECTION SITE PAPULE	53	6	31.51	8.00	3.44	18.60	53	6	31.61	8.01	3.45	18.64
VACCINATION COMPLICATION	2204	538	858.36	3.71	3.38	4.07	2204	538	861.91	3.72	3.38	4.08
INJECTION SITE IRRITATION	259	52	117.07	4.51	3.35	6.07	260	52	118.30	4.54	3.37	6.11
INJECTION SITE CELLULITIS	325	68	142.70	4.33	3.33	5.62	325	68	143.24	4.34	3.34	5.63
VACCINATION SITE ERYTHEMA	4842	1261	1782.44	3.48	3.27	3.70	4839	1254	1797.94	3.50	3.29	3.72
VACCINATION SITE												
LYMPHADENOPATHY	153	29	71.53	4.78	3.21	7.10	153	27	75.28	5.14	3.42	7.74
CELLULITIS	981	277	327.53	3.21	2.81	3.66	986	278	331.25	3.22	2.82	3.68
INJECTION SITE MASS	2285	680	720.97	3.04	2.79	3.31	2285	678	726.93	3.06	2.81	3.33

MULTIPLE USE OF SINGLE-USE PRODUCT	14	3	4.94	4.22	1.21	14.70	14	3	4.96	4.23	1.22	14.73
DENTAL DISCOMFORT	36	15	5.99	2.17	1.19	3.97	36	15	6.03	2.18	1.19	3.98
MYOSCLEROSIS	36	15	5.99	2.17	1.19	3.97	36	15	6.03	2.18	1.19	3.98
EPILEPSY	34	14	5.76	2.20	1.18	4.10	35	14	6.35	2.27	1.22	4.22
SKIN PLAQUE	28	11	5.08	2.30	1.15	4.63	28	11	5.11	2.31	1.15	4.64
EYE COLOUR CHANGE	19	6	4.64	2.87	1.14	7.18	19	5	5.85	3.45	1.29	9.23
ABSCESS LIMB	17	5	4.47	3.08	1.14	8.34	17	5	4.49	3.08	1.14	8.36
ECZEMA NUMMULAR	15	4	4.33	3.39	1.13	10.23	15	4	4.35	3.40	1.13	10.25
GENERALISED OEDEMA	22	8	4.42	2.49	1.11	5.59	22	7	5.48	2.85	1.22	6.68
SKIN HYPERTROPHY	20	7	4.22	2.59	1.09	6.12	20	7	4.24	2.59	1.10	6.13
INJECTION RELATED REACTION	18	6	4.02	2.72	1.08	6.84	17	6	3.44	2.57	1.01	6.52
ACCIDENTAL UNDERDOSE	206	1	181.77	186.47	26.14	1330.03	204	1	180.39	185.09	25.95	1320.29
VACCINATION SITE DYSAESTHESIA	20	1	13.72	18.10	2.43	134.89	20	1	13.76	18.15	2.44	135.21
PRODUCT CONTAMINATION PHYSICAL	19	1	12.84	17.20	2.30	128.47	19	1	12.88	17.24	2.31	128.77
VACCINATION SITE ANAESTHESIA	19	1	12.84	17.20	2.30	128.47	19	1	12.88	17.24	2.31	128.77
VACCINATION SITE HYPERSENSITIVITY	16	2	8.16	7.24	1.67	31.49	16	2	8.19	7.26	1.67	31.57
PRODUCT EXPIRATION DATE ISSUE	15	2	7.34	6.79	1.55	29.69	13	2	5.74	5.90	1.33	26.13
SARS-COV-2 ANTIBODY TEST	11	1	5.90	9.96	1.29	77.12	11	1	5.92	9.98	1.29	77.30
VACCINATION SITE STREAKING	11	2	4.17	4.98	1.10	22.46	11	2	4.19	4.99	1.11	22.51
SUPRAPUBIC PAIN	7	1	2.65	6.34	0.78	51.50	7	0	-	-	-	-
TISSUE INJURY	7	1	2.65	6.34	0.78	51.50	7	0	-	-	-	-

VAERS Pre-specified Conditions for COVID19 Reports, Automated Data (non-reviewed)
Initial domestic reports only, VAERS reports as of 04/29/2022 at 3PM

1

Condition	Age group							Total
	0-17	18-49	50-64	65-74	75-84	85+	UNK	
Acute Myocardial Infarction	20(00.6%)	685(20.3%)	820(24.2%)	779(23.0%)	541(16.0%)	315(09.3%)	222(06.6%)	3382
Anaphylaxis	83(03.1%)	1435(53.5%)	666(24.8%)	213(07.9%)	65(02.4%)	11(00.4%)	211(07.9%)	2684
Appendicitis	81(09.3%)	474(54.2%)	188(21.5%)	78(08.9%)	19(02.2%)	3(00.3%)	32(03.7%)	875
Bells Palsy	139(02.2%)	2434(39.3%)	1750(28.3%)	948(15.3%)	420(06.8%)	200(03.2%)	299(04.8%)	6190
COVID19								
Coagulopathy	159(01.3%)	3682(30.3%)	3175(26.1%)	2332(19.2%)	1284(10.6%)	501(04.1%)	1019(08.4%)	12152
Death	70(00.5%)	1044(07.3%)	2232(15.6%)	3250(22.7%)	3528(24.6%)	3011(21.0%)	1184(08.3%)	14319
Guillian-Barre Syndrome	32(02.9%)	377(33.7%)	330(29.5%)	177(15.8%)	86(07.7%)	16(01.4%)	101(09.0%)	1119
Kawasaki Disease	12(80.0%)	2(13.3%)		1(06.7%)				15
Multisystem Inflammatory Syndrome in Adults		80(25.1%)	65(20.4%)	94(29.5%)	54(16.9%)	26(08.2%)		319
Multisystem Inflammatory Syndrome in Children	165(90.2%)	18(09.8%)						183
Myopericarditis	876(18.8%)	2475(53.1%)	606(13.0%)	294(06.3%)	111(02.4%)	21(00.5%)	276(05.9%)	4659
Narcolepsy	2(04.4%)	16(35.6%)	12(26.7%)	7(15.6%)	1(02.2%)	1(02.2%)	6(13.3%)	45
Pregnant	108(01.2%)	7443(80.7%)	435(04.7%)	269(02.9%)	103(01.1%)	32(00.3%)	836(09.1%)	9226
Seizure	751(11.6%)	3562(55.0%)	966(14.9%)	526(08.1%)	286(04.4%)	129(02.0%)	260(04.0%)	6480
Stroke	32(00.7%)	759(15.6%)	1233(25.3%)	1127(23.1%)	867(17.8%)	467(09.6%)	391(08.0%)	4876
Transverse Myelitis	4(01.5%)	111(40.7%)	70(25.6%)	35(12.8%)	20(07.3%)	5(01.8%)	28(10.3%)	273
V-safe Serious	23(01.1%)	661(32.4%)	670(32.9%)	493(24.2%)	154(07.6%)	30(01.5%)	7(00.3%)	2038

**Primary Domestic VAERS COVID-19 Reports by Jurisdiction and Severity
Vaccinated and Received: December 14, 2020 - 04/08/2022 or missing
VAERS reports as of 04/08/2022 at 3PM
(N=806577)**

1

Jurisdiction	Estimated Population ^{1,2}	Death Reports ⁴ N(%)	Non-Death Serious Reports ⁵ N(%)	Non-Serious Reports N(%)	All Reports N
Alaska	731,545	33 (1.4)	102 (4.3)	2,236 (94.3)	2371
Alabama	4,903,185	84 (1.2)	419 (5.9)	6,620 (92.9)	7123
Arkansas	3,017,804	105 (2.2)	584 (12.3)	4,058 (85.5)	4747
Arizona	7,278,717	134 (0.8)	1,011 (6.0)	15,619 (93.2)	16764
California	39,512,223	644 (0.8)	4,792 (6.2)	71,906 (93.0)	77342
Colorado	5,758,736	116 (0.8)	1,176 (8.1)	13,308 (91.2)	14600
Connecticut	3,565,287	69 (0.7)	634 (6.1)	9,619 (93.2)	10322
District of Columbia	705,749	18 (0.9)	117 (5.8)	1,868 (93.3)	2003
Delaware	973,764	22 (1.0)	161 (7.4)	2,006 (91.6)	2189
Florida	21,477,737	520 (1.2)	4,232 (9.5)	39,873 (89.4)	44625
Georgia	10,617,423	342 (1.9)	1,434 (7.8)	16,678 (90.4)	18454
Hawaii	1,415,872	42 (1.4)	200 (6.6)	2,768 (92.0)	3010
Iowa	3,155,070	103 (1.7)	564 (9.5)	5,283 (88.8)	5950
Idaho	1,787,065	29 (0.8)	235 (6.7)	3,259 (92.5)	3523
Illinois	12,671,821	339 (1.3)	2,171 (8.6)	22,791 (90.1)	25301
Indiana	6,732,219	159 (0.6)	826 (3.1)	25,618 (96.3)	26603
Kansas	2,913,314	81 (1.4)	399 (6.9)	5,312 (91.7)	5792
Kentucky	4,467,673	741 (6.4)	1,895 (16.3)	9,020 (77.4)	11656
Louisiana	4,648,794	77 (1.2)	429 (6.8)	5,840 (92.0)	6346
Massachusetts	6,892,503	148 (0.8)	1,261 (7.0)	16,626 (92.2)	18035
Maryland	6,045,680	136 (0.9)	1,210 (7.9)	13,983 (91.2)	15329
Maine	1,344,212	39 (1.0)	240 (6.1)	3,666 (92.9)	3945
Michigan	9,986,857	650 (2.4)	5,832 (21.5)	20,697 (76.2)	27179
Minnesota	5,639,632	453 (2.5)	3,340 (18.7)	14,102 (78.8)	17895
Missouri	6,137,428	258 (2.1)	1,232 (9.9)	10,959 (88.0)	12449

¹ Source for Estimated State Data: <https://www.census.gov/data/tables/time-series/demo/popest/2010s-state-total.html>

² Source for 2018 Estimated Freely Associated States and Guam Data: <https://sdd.spc.int/>

³ Source for 2020 Estimated US Virgin Islands Data: <https://www.worldometers.info/world-population/united-states-virgin-islands-population/>

⁴ Death Reports include unconfirmed reports of death. Some cases are pending confirmation by autopsy, medical record, or death certificate (VAERS form Item 21)

⁵ Non-Death Serious reports include reports of life-threatening conditions, hospitalization, extended hospitalization, permanent disability, or birth defect (VAERS form Item 21)

**Primary Domestic VAERS COVID-19 Reports by Jurisdiction and Severity
Vaccinated and Received: December 14, 2020 - 04/08/2022 or missing
VAERS reports as of 04/08/2022 at 3PM
(N=806577)**

Jurisdiction	Estimated Population^{1,2}	Death Reports⁴ N(%)	Non-Death Serious Reports⁵ N(%)	Non-Serious Reports N(%)	All Reports N
Mississippi	2,976,149	63 (1.8)	199 (5.8)	3,195 (92.4)	3457
Montana	1,068,778	113 (3.6)	524 (16.5)	2,539 (79.9)	3176
North Carolina	10,488,084	168 (0.8)	1,464 (7.4)	18,241 (91.8)	19873
North Dakota	762,062	39 (2.3)	294 (17.4)	1,361 (80.3)	1694
Nebraska	1,934,408	58 (1.6)	278 (7.8)	3,239 (90.6)	3575
New Hampshire	1,359,711	84 (2.1)	291 (7.4)	3,565 (90.5)	3940
New Jersey	8,882,190	200 (0.9)	1,748 (7.6)	21,120 (91.6)	23068
New Mexico	2,096,829	51 (1.1)	236 (5.1)	4,332 (93.8)	4619
Nevada	3,080,156	44 (0.8)	428 (8.1)	4,824 (91.1)	5296
New York	19,453,561	376 (0.9)	3,060 (7.1)	39,380 (92.0)	42816
Ohio	11,689,100	330 (1.4)	2,040 (8.7)	21,012 (89.9)	23382
Oklahoma	3,956,971	138 (1.8)	606 (7.8)	7,052 (90.5)	7796
Oregon	4,217,737	84 (0.8)	737 (6.9)	9,791 (92.3)	10612
Pennsylvania	12,801,989	285 (1.0)	2,033 (7.2)	25,803 (91.8)	28121
Rhode Island	1,059,361	21 (0.8)	163 (6.4)	2,381 (92.8)	2565
South Carolina	5,148,714	74 (0.9)	563 (7.0)	7,398 (92.1)	8035
South Dakota	884,659	144 (8.8)	109 (6.6)	1,390 (84.6)	1643
Tennessee	6,829,174	874 (7.2)	953 (7.8)	10,353 (85.0)	12180
Texas	28,995,881	726 (1.6)	2,864 (6.5)	40,805 (91.9)	44395
Utah	3,205,958	38 (0.7)	351 (6.4)	5,072 (92.9)	5461
Virginia	8,535,519	161 (0.9)	1,270 (6.9)	16,971 (92.2)	18402
Vermont	623,989	15 (0.7)	108 (5.2)	1,951 (94.1)	2074
Washington	7,614,893	209 (1.1)	1,474 (7.7)	17,366 (91.2)	19049
Wisconsin	5,822,434	405 (2.9)	1,384 (9.8)	12,351 (87.3)	14140
West Virginia	1,792,147	67 (2.2)	292 (9.6)	2,677 (88.2)	3036

¹ Source for Estimated State Data: <https://www.census.gov/data/tables/time-series/demo/popest/2010s-state-total.html>

² Source for 2018 Estimated Freely Associated States and Guam Data: <https://sdd.spc.int/>

³ Source for 2020 Estimated US Virgin Islands Data: <https://www.worldometers.info/world-population/united-states-virgin-islands-population/>

⁴ Death Reports include unconfirmed reports of death. Some cases are pending confirmation by autopsy, medical record, or death certificate (VAERS form Item 21)

⁵ Non-Death Serious reports include reports of life-threatening conditions, hospitalization, extended hospitalization, permanent disability, or birth defect (VAERS form Item 21)

Primary Domestic VAERS COVID-19 Reports by Jurisdiction and Severity
Vaccinated and Received: December 14, 2020 - 04/08/2022 or missing
VAERS reports as of 04/08/2022 at 3PM
(N=806577)

Jurisdiction	Estimated Population¹²³	Death Reports⁴ N(%)	Non-Death Serious Reports⁵ N(%)	Non-Serious Reports N(%)	All Reports N
Wyoming	578,759	24 (2.4)	77 (7.8)	892 (89.8)	993
Not Specified	NA	2,771 (2.6)	9,972 (9.5)	92,237 (87.9)	104980
United States	328,239,523	12,904 (1.6)	68,014 (8.5)	721,013 (89.9)	801931
American Samoa	56,700	1 (2.9)	2 (5.7)	32 (91.4)	35
Federated States of Micronesia	105,300		2 (40.0)	3 (60.0)	5
Guam	172,400	4 (2.4)	14 (8.5)	147 (89.1)	165
Republic of the Marshall Islands	55,500		1 (16.7)	5 (83.3)	6
Commonwealth of the Northern Mariana Islands	56,200	11 (28.2)	5 (12.8)	23 (59.0)	39
Puerto Rico	3,193,694	118 (2.7)	160 (3.7)	4,015 (93.5)	4293
Republic of Palau	17,900			2 (100.0)	2
QM	NA			2 (100.0)	2
QW	NA			1 (100.0)	1
Tx	NA			1 (100.0)	1
U.S. Virgin Islands	104,433		5 (5.4)	88 (94.6)	93
XB	NA		1 (50.0)	1 (50.0)	2
XV	NA		1 (50.0)	1 (50.0)	2

¹ Source for Estimated State Data: <https://www.census.gov/data/tables/time-series/demo/popest/2010s-state-total.html>

² Source for 2018 Estimated Freely Associated States and Guam Data: <https://sdd.spc.int/>

³ Source for 2020 Estimated US Virgin Islands Data: <https://www.worldometers.info/world-population/united-states-virgin-islands-population/>

⁴ Death Reports include unconfirmed reports of death. Some cases are pending confirmation by autopsy, medical record, or death certificate (VAERS form Item 21)

⁵ Non-Death Serious reports include reports of life-threatening conditions, hospitalization, extended hospitalization, permanent disability, or birth defect (VAERS form Item 21)

PREFERRED Medical Dictionary for Regulatory Activities (MedDRA) Terms (VAERS-1 Box 7, VAERS 2.0 Box 18)

For Current Week and Past Week Comparison

Following **ALL 12/14/2020-04/08/2022 COVID19 Pfizer Ages 18+ Vaccines**

Compared to **ALL 12/14/2020-04/08/2022 COVID19 Moderna Ages 18+ Vaccines**

AGES 18+ YEARS, Initial domestic reports only, VAERS reports as of 04/08/2022

Vaccination, Received, and Completed Date: 12/14 - 04/08 (Current Week) and 12/14 - 04/01 (Past Week)

N₁≥3 (Current Week), PRR₁≥2.00 (Ratio of Proportions), Chi-Square₁≥4.00

MedDRA PTs sorting based on lower confidence limit and PFIZER adverse event count from 12/14/2020-04/08/2022

AGES 18+ YEARS excludes missing ages

MedDRA Codes ALL Reports (18+)	12/14/2020- 04/08/2022 PFIZER N=302401	12/14/2020- 04/08/2022 MODERNA N=322944	12/14-04/08 Chi-Square	12/14-04/08 PRR	12/14-04/08 LCL	12/14-04/08 UCL	12/14/2020- 04/01/2022 PFIZER N=301241	12/14/2020- 04/01/2022- 04/01/2022 MODERNA N=321994	12/14-04/01 Chi-Square	12/14-04/01 PRR	12/14-04/01 LCL	12/14-04/01 UCL
PRODUCT PREPARATION ERROR	559	15	551.07	39.80	23.83	66.46	558	15	550.52	39.76	23.81	66.40
VACCINATION FAILURE	973	51	892.40	20.37	15.38	27.00	953	45	888.21	22.64	16.79	30.52
PRODUCT USE ISSUE	432	27	383.32	17.09	11.58	25.21	431	27	382.66	17.06	11.57	25.17
PRODUCT PREPARATION ISSUE	2107	167	1791.64	13.47	11.51	15.77	2107	167	1793.53	13.49	11.52	15.79
DISEASE RECURRENCE	215	11	196.20	20.87	11.39	38.26	215	11	196.40	20.89	11.40	38.29
IMMUNISATION	2515	215	2101.47	12.49	10.87	14.36	2512	215	2100.56	12.49	10.87	14.35
CIRCUMSTANCE OR INFORMATION CAPABLE OF LEADING TO MEDICATION ERROR	124	17	86.92	7.79	4.69	12.93	123	17	86.01	7.73	4.66	12.84
OFF LABEL USE	972	211	541.07	4.92	4.24	5.71	965	211	535.20	4.89	4.21	5.67
IMMUNODEFICIENCY	480	107	261.35	4.79	3.89	5.91	481	105	266.14	4.90	3.96	6.05
DRUG INEFFECTIVE	1021	266	494.21	4.10	3.58	4.69	1014	259	499.80	4.18	3.65	4.80
APPARENT LIFE THREATENING EVENT	64	10	41.57	6.83	3.51	13.31	64	10	41.62	6.84	3.51	13.32
INCORRECT PRODUCT FORMULATION ADMINISTERED	548	162	235.35	3.61	3.03	4.30	548	162	235.72	3.62	3.03	4.31
MIDDLE INSOMNIA	75	17	39.21	4.71	2.78	7.98	75	17	39.26	4.72	2.79	7.98
OVERDOSE	176	56	69.21	3.36	2.48	4.53	176	56	69.32	3.36	2.49	4.54
INTERCHANGE OF VACCINE PRODUCTS	5777	2635	1408.73	2.34	2.24	2.45	5768	2615	1425.09	2.36	2.25	2.47
WHITE BLOOD CELL COUNT INCREASED	112	37	41.83	3.23	2.23	4.69	111	36	42.40	3.30	2.26	4.80
NEAR DEATH EXPERIENCE	106	35	39.55	3.23	2.21	4.74	105	35	38.81	3.21	2.19	4.70
CROHN'S DISEASE	126	45	42.93	2.99	2.13	4.20	123	45	40.66	2.92	2.08	4.11
DRUG HYPERSENSITIVITY	180	74	50.65	2.60	1.98	3.40	180	71	54.02	2.71	2.06	3.57
SKIN DISORDER	266	118	66.46	2.41	1.94	2.99	265	115	68.89	2.46	1.98	3.07
ANTINUCLEAR ANTIBODY POSITIVE	29	7	13.68	4.42	1.94	10.10	28	7	12.81	4.28	1.87	9.79
EXPOSURE TO SARS-COV-2	1227	617	244.11	2.12	1.93	2.34	1212	610	241.26	2.12	1.93	2.34
POLYMENORRHOEA	462	219	102.85	2.25	1.92	2.65	461	219	102.44	2.25	1.92	2.64
UTERINE HAEMORRHAGE	64	22	22.36	3.11	1.91	5.04	64	22	22.40	3.11	1.92	5.05
MENSTRUAL DISORDER	1598	829	297.58	2.06	1.89	2.24	1597	828	298.55	2.06	1.90	2.24
FAR DISORDER	108	43	31.54	2.68	1.88	3.82	106	43	30.13	2.63	1.85	3.76
CLAUSTROPHOBIA	23	5	11.48	4.91	1.87	12.92	23	5	11.50	4.92	1.87	12.93
INTERMENSTRUAL BLEEDING	862	445	161.66	2.07	1.85	2.32	860	443	162.48	2.08	1.85	2.33
ELECTROCARDIOGRAM ABNORMAL	77	29	24.07	2.84	1.85	4.35	74	28	22.99	2.82	1.83	4.36
HYPOMENORRHOEA	116	48	31.99	2.58	1.84	3.61	115	48	31.34	2.56	1.83	3.59
UPPER RESPIRATORY TRACT CONGESTION	101	42	27.53	2.57	1.79	3.68	100	42	26.87	2.54	1.77	3.65
VIBRATORY SENSE INCREASED	64	24	19.97	2.85	1.78	4.55	63	24	19.25	2.81	1.75	4.49

MAST CELL ACTIVATION SYNDROME	49	17	16.69	3.08	1.77	5.34	49	16	17.98	3.27	1.86	5.76
PHARYNGEAL INFLAMMATION	17	3	9.34	6.05	1.77	20.65	17	3	9.35	6.06	1.78	20.67
BONE DISORDER	40	13	14.54	3.29	1.76	6.14	40	12	15.89	3.56	1.87	6.79
STRIDOR	122	54	30.14	2.41	1.75	3.32	122	54	30.20	2.41	1.75	3.33
WEIGHT FLUCTUATION	24	6	10.79	4.27	1.75	10.45	23	6	9.94	4.10	1.67	10.06
APPENDICITIS	405	215	70.85	2.01	1.71	2.37	405	215	71.04	2.01	1.71	2.38
NERVE COMPRESSION	138	66	29.64	2.23	1.67	2.99	137	66	29.07	2.22	1.65	2.98
FACIAL SPASM	72	30	19.31	2.56	1.67	3.92	73	30	20.06	2.60	1.70	3.98
BASEDOW'S DISEASE	90	40	21.86	2.40	1.66	3.49	88	40	20.56	2.35	1.62	3.42
ANGIOGRAM	16	3	8.40	5.70	1.66	19.55	16	3	8.41	5.70	1.66	19.56
FIBRIN D DIMER INCREASED	99	45	23.17	2.35	1.65	3.34	97	45	21.90	2.30	1.62	3.28
BLOOD CHOLESTEROL INCREASED	78	34	19.48	2.45	1.64	3.66	78	34	19.52	2.45	1.64	3.67
WHITE BLOOD CELL COUNT DECREASED	59	24	16.27	2.63	1.63	4.22	59	24	16.30	2.63	1.63	4.22
LIVE BIRTH	29	9	10.80	3.44	1.63	7.27	29	9	10.82	3.44	1.63	7.28
BLOOD LACTIC ACID INCREASED	18	4	8.57	4.81	1.63	14.20	17	4	7.69	4.54	1.53	13.50
BODY TEMPERATURE ABNORMAL	115	55	24.57	2.23	1.62	3.08	115	55	24.63	2.23	1.62	3.08
HAEMOGLOBIN DECREASED	70	30	17.90	2.49	1.62	3.82	70	30	17.94	2.49	1.62	3.83
CEREBROVASCULAR DISORDER	35	12	11.81	3.11	1.62	6.00	35	12	11.83	3.12	1.62	6.01
NORMAL LABOUR	33	11	11.46	3.20	1.62	6.34	26	9	8.43	3.09	1.45	6.59
PERITONITIS	33	11	11.46	3.20	1.62	6.34	33	11	11.48	3.21	1.62	6.34
VACCINATION SITE HYPOAESTHESIA	48	19	13.63	2.70	1.59	4.59	47	19	12.93	2.64	1.55	4.50
SUPPRESSED LACTATION	89	42	19.34	2.26	1.57	3.27	89	42	19.39	2.27	1.57	3.27
PUPILLARY REFLEX IMPAIRED	64	28	15.73	2.44	1.57	3.81	64	28	15.77	2.44	1.57	3.81
RED BLOOD CELL COUNT DECREASED	30	10	10.33	3.20	1.57	6.55	30	10	10.35	3.21	1.57	6.56
VOCAL CORD PARALYSIS	28	9	9.99	3.32	1.57	7.04	28	9	10.01	3.33	1.57	7.05
VENTRICULAR ARRHYTHMIA	26	8	9.66	3.47	1.57	7.67	25	8	8.87	3.34	1.51	7.41
PHARYNGEAL MASS	15	3	7.47	5.34	1.55	18.44	15	3	7.48	5.34	1.55	18.46
PNEUMONIA PSEUDOMONAL	15	3	7.47	5.34	1.55	18.44	14	3	6.57	4.99	1.43	17.36
VIRAL SEPSIS	17	4	7.68	4.54	1.53	13.49	17	4	7.69	4.54	1.53	13.50
APPENDICITIS PERFORATED	76	36	16.28	2.25	1.52	3.35	76	36	16.32	2.26	1.52	3.35
OSTEOPENIA	35	13	10.63	2.88	1.52	5.43	35	13	10.65	2.88	1.52	5.44
LACTATION DISORDER	33	12	10.26	2.94	1.52	5.69	33	12	10.28	2.94	1.52	5.69
WRONG PATIENT	33	12	10.26	2.94	1.52	5.69	33	12	10.28	2.94	1.52	5.69
GASTRIC DISORDER	101	51	19.20	2.11	1.51	2.96	101	51	19.25	2.12	1.51	2.96
CONVALESCENT PLASMA TRANSFUSION	44	18	11.80	2.61	1.51	4.52	43	18	11.12	2.55	1.47	4.43
BLOOD BILIRUBIN INCREASED	25	8	8.85	3.34	1.51	7.40	25	7	10.21	3.82	1.65	8.83
RENAL TRANSPLANT	21	6	8.22	3.74	1.51	9.26	21	6	8.23	3.74	1.51	9.27
RED BLOOD CELL SEDIMENTATION RATE INCREASED	36	14	10.27	2.75	1.48	5.09	36	14	10.29	2.75	1.48	5.10
C-REACTIVE PROTEIN INCREASED	57	26	12.92	2.34	1.47	3.72	56	25	13.22	2.39	1.49	3.84
AUTONOMIC NERVOUS SYSTEM IMBALANCE	94	49	16.61	2.05	1.45	2.89	93	49	16.06	2.03	1.44	2.87
OVARIAN CYST	94	49	16.61	2.05	1.45	2.89	94	49	16.65	2.05	1.45	2.90
BASAL GANGLIA INFARCTION	28	10	8.77	2.99	1.45	6.16	28	10	8.79	2.99	1.45	6.16
ABNORMAL UTERINE BLEEDING	56	26	12.26	2.30	1.44	3.66	56	26	12.29	2.30	1.45	3.67
MASTITIS	67	33	13.18	2.17	1.43	3.29	67	33	13.22	2.17	1.43	3.29
WOUND DRAINAGE	22	7	7.72	3.36	1.43	7.86	22	7	7.73	3.36	1.44	7.86

CERUMEN IMPACTION	20	6	7.39	3.56	1.43	8.86	20	6	7.40	3.56	1.43	8.87
MAGNETIC RESONANCE IMAGING HEART	20	6	7.39	3.56	1.43	8.86	19	6	6.59	3.38	1.35	8.48
PHARYNGEAL DISORDER	20	6	7.39	3.56	1.43	8.86	20	6	7.40	3.56	1.43	8.87
IFEMIANAESTHESIA	18	5	7.08	3.84	1.43	10.35	18	5	7.09	3.85	1.43	10.36
ENDOTRACHEAL INTUBATION COMPLICATION	16	4	6.80	4.27	1.43	12.78	16	4	6.81	4.28	1.43	12.79
NEUTROPHIL COUNT DECREASED	16	4	6.80	4.27	1.43	12.78	16	4	6.81	4.28	1.43	12.79
SLEEP DISORDER DUE TO A GENERAL MEDICAL CONDITION	14	3	6.56	4.98	1.43	17.34	14	3	6.57	4.99	1.43	17.36
COMA SCALE ABNORMAL	71	36	13.17	2.11	1.41	3.15	71	34	14.88	2.23	1.48	3.36
HANGOVER	58	28	11.79	2.21	1.41	3.47	58	28	11.82	2.21	1.41	3.48
BLADDER DISORDER	53	25	11.22	2.26	1.41	3.64	51	24	10.84	2.27	1.40	3.69
NONINFECTIVE ENCEPHALITIS	29	11	8.39	2.82	1.41	5.64	28	10	8.79	2.99	1.45	6.16
INTRACRANIAL PRESSURE INCREASED	41	18	9.72	2.43	1.40	4.23	41	19	8.83	2.31	1.34	3.97
HORMONE LEVEL ABNORMAL	65	33	11.96	2.10	1.38	3.20	65	33	11.99	2.11	1.38	3.20
SUBMAXILLARY GLAND ENLARGEMENT	25	9	7.65	2.97	1.38	6.36	25	9	7.66	2.97	1.39	6.36
VISUAL ACUTY REDUCED	50	24	10.18	2.22	1.37	3.62	50	23	11.09	2.32	1.42	3.81
PHARYNGEAL ULCERATION	23	8	7.28	3.07	1.37	6.86	23	8	7.30	3.07	1.37	6.87
RED BLOOD CELL TRANSFUSION	26	10	7.28	2.78	1.34	5.76	21	8	5.80	2.81	1.24	6.33
AORTIC DISORDER	17	5	6.25	3.63	1.34	9.84	17	5	6.26	3.63	1.34	9.85
NASAL PRURITUS	58	30	10.17	2.06	1.33	3.21	58	30	10.19	2.07	1.33	3.21
PROTEINURIA	58	30	10.17	2.06	1.33	3.21	58	29	10.99	2.14	1.37	3.34
MEASLES	15	4	5.95	4.00	1.33	12.07	15	4	5.96	4.01	1.33	12.08
NAIL DISCOLOURATION	59	31	9.98	2.03	1.32	3.14	58	30	10.19	2.07	1.33	3.21
THYROIDITIS	50	25	9.35	2.14	1.32	3.45	50	25	9.37	2.14	1.32	3.46
AZOTAEMIA	39	18	8.40	2.31	1.32	4.04	36	17	7.38	2.26	1.27	4.03
STILLBIRTH	39	18	8.40	2.31	1.32	4.04	39	18	8.42	2.32	1.32	4.05
DECREASED NASOLABIAL FOLD	24	9	6.90	2.85	1.32	6.13	24	9	6.92	2.85	1.32	6.13
COLOSTOMY	13	3	5.68	4.63	1.32	16.24	13	3	5.69	4.63	1.32	16.25
GESTATIONAL DIABETES	22	8	6.53	2.94	1.31	6.60	22	8	6.54	2.94	1.31	6.60
PHARYNGITIS STREPTOCOCCAL	57	30	9.58	2.03	1.30	3.16	57	30	9.61	2.03	1.31	3.16
ACUTE CARDIAC EVENT	27	11	6.96	2.62	1.30	5.28	27	11	6.97	2.62	1.30	5.29
TIC	49	25	8.75	2.09	1.29	3.39	49	24	9.58	2.18	1.34	3.56
FEBRILE NEUTROPENIA	35	16	7.60	2.34	1.29	4.22	35	16	7.62	2.34	1.29	4.22
BLOOD THYROID STIMULATING HORMONE INCREASED	30	13	7.06	2.46	1.29	4.72	30	13	7.08	2.47	1.29	4.73
CARDIAC VALVE DISEASE	30	13	7.06	2.46	1.29	4.72	30	12	8.07	2.67	1.37	5.22
DEPERSONALISATION/DEREALISATION DISORDER	30	13	7.06	2.46	1.29	4.72	30	13	7.08	2.47	1.29	4.73
ANKYLOSING SPONDYLITIS	25	10	6.57	2.67	1.28	5.56	25	10	6.58	2.67	1.28	5.56
ENDOMETRIAL THICKENING	25	10	6.57	2.67	1.28	5.56	23	10	5.21	2.46	1.17	5.17
EYE OEDEMA	25	10	6.57	2.67	1.28	5.56	25	9	7.66	2.97	1.39	6.36
PETIT MAL EPILEPSY	28	12	6.66	2.49	1.27	4.90	28	12	6.68	2.49	1.27	4.90
LABILE BLOOD PRESSURE	18	6	5.80	3.20	1.27	8.07	18	6	5.81	3.21	1.27	8.08
PLATELET COUNT INCREASED	31	14	6.80	2.36	1.26	4.44	31	14	6.81	2.37	1.26	4.45
OCULAR ICTERUS	37	18	7.14	2.20	1.25	3.86	36	18	6.55	2.14	1.21	3.76
NIH STROKE SCALE	34	16	6.96	2.27	1.25	4.11	33	15	7.21	2.35	1.28	4.33
WOUND INFECTION	26	11	6.26	2.52	1.25	5.11	24	11	4.96	2.33	1.14	4.76
FACTOR V LEIDEN MUTATION	16	5	5.45	3.42	1.25	9.33	15	5	4.68	3.21	1.17	8.82

UTERINE PAIN	38	19	6.94	2.14	1.23	3.70	37	19	6.36	2.08	1.20	3.62
ANTIALLERGIC THERAPY	32	15	6.56	2.28	1.23	4.21	32	15	6.57	2.28	1.23	4.21
ELECTROCARDIOGRAM ST SEGMENT ABNORMAL	32	15	6.56	2.28	1.23	4.21	32	14	7.47	2.44	1.30	4.58
BLOOD SODIUM DECREASED	24	10	5.87	2.56	1.23	5.36	24	10	5.88	2.57	1.23	5.36
HAEMOTHORAX	14	4	5.12	3.74	1.23	11.36	14	4	5.13	3.74	1.23	11.37
PARENTERAL NUTRITION	14	4	5.12	3.74	1.23	11.36	14	4	5.13	3.74	1.23	11.37
CORONARY ANGIOPLASTY	27	12	5.99	2.40	1.22	4.74	27	12	6.01	2.41	1.22	4.75
COR PULMONALE	19	7	5.41	2.90	1.22	6.90	19	7	5.42	2.90	1.22	6.90
ESCHERICHIA URINARY TRACT INFECTION	19	7	5.41	2.90	1.22	6.90	18	7	4.70	2.75	1.15	6.58
POSTPARTUM HAEMORRHAGE	19	7	5.41	2.90	1.22	6.90	19	7	5.42	2.90	1.22	6.90
DYSAESTHESIA	36	18	6.53	2.14	1.21	3.76	35	18	5.96	2.08	1.18	3.67
EPICONDYLITIS	30	14	6.15	2.29	1.21	4.32	29	14	5.54	2.21	1.17	4.19
ALANINE AMINOTRANSFERASE INCREASED	40	21	6.57	2.03	1.20	3.45	40	20	7.36	2.14	1.25	3.66
ABDOMINAL MASS	23	9	5.47	2.61	1.20	5.67	22	9	5.49	2.61	1.20	5.67
PROTEIN URINE PRESENT	17	6	5.04	3.03	1.19	7.67	17	6	5.05	3.03	1.19	7.68
SOCIAL AVOIDANT BEHAVIOUR	20	8	5.08	2.67	1.18	6.06	20	8	5.09	2.67	1.18	6.07
CONVERSION DISORDER	32	16	5.73	2.14	1.17	3.89	32	16	5.75	2.14	1.17	3.90
WALKING DISABILITY	32	16	5.73	2.14	1.17	3.89	32	15	6.57	2.28	1.23	4.21
PELVIC VENOUS THROMBOSIS	26	12	5.35	2.31	1.17	4.59	26	12	5.36	2.32	1.17	4.59
INCORRECT PRODUCT ADMINISTRATION DURATION	23	10	5.19	2.46	1.17	5.16	23	10	5.21	2.46	1.17	5.17
MITRAL VALVE CALCIFICATION	23	10	5.19	2.46	1.17	5.16	22	10	4.55	2.35	1.11	4.97
PHONOPHOBIA	23	10	5.19	2.46	1.17	5.16	23	10	5.21	2.46	1.17	5.17
SICK RELATIVE	36	19	5.77	2.02	1.16	3.53	36	18	6.55	2.14	1.21	3.76
COMPLICATED APPENDICITIS	15	5	4.67	3.20	1.16	8.81	15	5	4.68	3.21	1.17	8.82
COMPUTERISED TOMOGRAPHY THORAX	15	5	4.67	3.20	1.16	8.81	15	5	4.68	3.21	1.17	8.82
FOETAL HYPOKINESIA	33	17	5.55	2.07	1.15	3.72	32	17	4.99	2.01	1.12	3.62
HEPATIC MASS	30	15	5.33	2.14	1.15	3.97	30	14	6.17	2.29	1.21	4.32
SPINAL DISORDER	30	15	5.33	2.14	1.15	3.97	29	15	4.76	2.07	1.11	3.85
VERTEBRAL ARTERY DISSECTION	18	7	4.60	2.75	1.15	6.57	18	7	4.70	2.75	1.15	6.58
CLONUS	27	13	5.13	2.22	1.14	4.30	26	13	4.54	2.14	1.10	4.16
HYPOSMOLAR STATE	27	13	5.13	2.22	1.14	4.30	27	13	5.14	2.22	1.15	4.30
NIH STROKE SCALE SCORE INCREASED	27	13	5.13	2.22	1.14	4.30	27	13	5.14	2.22	1.15	4.30
BLOOD CREATINE PHOSPHOKINASE INCREASED	24	11	4.95	2.33	1.14	4.76	24	11	4.96	2.33	1.14	4.76
CERVICAL RADICULOPATHY	24	11	4.95	2.33	1.14	4.76	24	11	4.96	2.33	1.14	4.76
INTESTINAL PERFORATION	24	11	4.95	2.33	1.14	4.76	24	11	4.96	2.33	1.14	4.76
RENAL MASS	21	9	4.79	2.49	1.14	5.44	21	9	4.80	2.49	1.14	5.45
HEARING AID USER	31	16	5.15	2.07	1.13	3.78	31	14	6.81	2.37	1.26	4.45
PENILE PAIN	13	4	4.31	3.47	1.13	10.64	13	4	4.32	3.47	1.13	10.65
BRONCHIAL SECRETION RETENTION	29	15	4.75	2.06	1.11	3.85	28	14	4.94	2.14	1.13	4.06
MICROCYTIC ANAEMIA	29	15	4.75	2.06	1.11	3.85	29	15	4.76	2.07	1.11	3.85
THYROID PAIN	22	10	4.54	2.35	1.11	4.96	22	10	4.55	2.35	1.11	4.97
MENTINGITIS VIRAL	19	8	4.39	2.54	1.11	5.79	19	8	4.40	2.54	1.11	5.80
MUSCLE RUPTURE	19	8	4.39	2.54	1.11	5.79	19	8	4.40	2.54	1.11	5.80
ORTHOSTATIC HYPERTENSION	19	8	4.39	2.54	1.11	5.79	19	8	4.40	2.54	1.11	5.80
BLOOD POTASSIUM INCREASED	16	6	4.30	2.85	1.11	7.28	16	6	4.31	2.85	1.12	7.28
CIRRHOSIS ALCOHOLIC	16	6	4.30	2.85	1.11	7.28	16	6	4.31	2.85	1.12	7.28

PATIENT UNCOOPERATIVE	26	13	4.53	2.14	1.10	4.16	26	13	4.54	2.14	1.10	4.16
ALCOHOL WITHDRAWAL SYNDROME	23	11	4.32	2.23	1.09	4.58	23	11	4.33	2.23	1.09	4.58
LANGUAGE DISORDER	23	11	4.32	2.23	1.09	4.58	23	11	4.33	2.23	1.09	4.58
ILLUSION	20	9	4.14	2.37	1.08	5.21	20	9	4.15	2.38	1.08	5.22
CEREBRAL ARTERY STENOSIS	24	12	4.13	2.14	1.07	4.27	24	12	4.14	2.14	1.07	4.27
MENISCUS INJURY	24	12	4.13	2.14	1.07	4.27	24	12	4.14	2.14	1.07	4.27
POSTURAL ORTHOSTATIC TACHYCARDIA SYNDROME	142	75	24.68	2.02	1.53	2.67	138	74	23.19	1.99	1.50	2.64
VEIN DISORDER	87	46	14.83	2.03	1.41	2.89	86	46	14.29	2.00	1.40	2.86
ALOPECIA ARIATA	66	35	11.00	2.01	1.34	3.03	64	35	9.91	1.95	1.29	2.95
PNEUMOMEDIASTUM	33	17	5.55	2.07	1.15	3.72	31	17	3.72	1.08	1.03	3.52
PNEUMOPERITONEUM	18	7	4.69	2.75	1.15	6.57	16	7	3.34	2.44	1.01	5.94
POSTPARTUM STATE	13	4	4.31	3.47	1.13	10.64	12	4	3.55	3.21	1.03	9.94
THERAPEUTIC PRODUCT EFFECT DECREASED	13	4	4.31	3.47	1.13	10.64	12	4	3.55	3.21	1.03	9.94
LABORATORY TEST ABNORMAL	29	15	4.75	2.06	1.11	3.85	28	15	4.20	2.00	1.07	3.74
NECROSIS	19	8	4.39	2.54	1.11	5.70	18	8	3.75	2.41	1.05	5.53
COMPLICATION OF PREGNANCY	16	6	4.30	2.85	1.11	7.28	15	6	3.61	2.67	1.04	6.89
HYDRADENITIS	23	11	4.32	2.23	1.09	4.58	20	10	3.34	2.14	1.00	4.57
CORRECTIVE LENS USER	20	9	4.14	2.37	1.08	5.21	19	9	3.53	2.26	1.02	4.99
BODY HEIGHT DECREASED	55	2	50.98	39.37	7.16	120.40	55	2	51.03	29.39	7.17	120.50
PRODUCT LOT NUMBER ISSUE	25	1	21.91	26.70	3.62	197.03	25	1	21.93	26.72	3.62	197.21
SALIVARY GLAND PAIN	18	2	12.27	9.61	2.23	41.42	18	2	12.29	9.62	2.23	41.46
PNELMOTIORAX	17	2	11.27	9.08	2.10	39.29	16	2	10.29	8.55	1.97	37.19
SPONTANEOUS	13	2	7.35	6.94	1.57	30.76	13	2	7.36	6.95	1.57	30.79
ELDERLY	13	2	7.35	6.94	1.57	30.76	13	2	7.36	6.95	1.57	30.79
LYMPHOCYTE COUNT DECREASED	13	2	7.35	6.94	1.57	30.76	13	2	7.36	6.95	1.57	30.79
OCULAR VASCULAR DISORDER	13	2	7.35	6.94	1.57	30.76	13	2	7.36	6.95	1.57	30.79
CEREBROSPINAL FLUID LEAKAGE	11	1	7.36	11.75	1.52	90.99	11	1	7.37	11.76	1.52	91.07
CYST RUPTURE	12	2	6.40	6.41	1.43	28.63	12	2	6.41	6.41	1.44	28.65
HYPOAESTHESIA TETH	12	2	6.40	6.41	1.43	28.63	12	2	6.41	6.41	1.44	28.65
INTERVERTEBRAL DISCITIS	12	2	6.40	6.41	1.43	28.63	12	2	6.41	6.41	1.44	28.65
MENORRHAGIA	12	2	6.40	6.41	1.43	28.63	12	2	6.41	6.41	1.44	28.65
ALOPECIA UNIVERSALIS	10	1	6.36	10.68	1.37	83.42	10	1	6.37	10.69	1.37	83.50
ENTEROBACTER INFECTION	10	1	6.36	10.68	1.37	83.42	10	1	6.37	10.69	1.37	83.50
THERAPEUTIC RESPONSE	10	1	6.36	10.68	1.37	83.42	10	1	6.37	10.69	1.37	83.50
SHORTENED	10	1	6.36	10.68	1.37	83.42	9	1	5.38	9.62	1.22	75.93
ACUTE STRESS DISORDER	11	2	5.47	5.87	1.30	26.50	11	2	5.48	5.88	1.30	26.52
BLOOD MAGNESIUM	11	2	5.47	5.87	1.30	26.50	11	2	5.48	5.88	1.30	26.52
DECREASED	11	2	5.47	5.87	1.30	26.50	11	2	5.48	5.88	1.30	26.52
MUTISM	11	2	5.47	5.87	1.30	26.50	11	2	5.48	5.88	1.30	26.52
CHRONIC PIGMENTED PURPURA	9	1	5.38	9.61	1.22	75.86	9	1	5.38	9.62	1.22	75.93
GASTRITIS PROSIVE	9	1	5.38	9.61	1.22	75.86	9	1	5.38	9.62	1.22	75.93
OBSTRUCTIVE SLEEP APNOEA SYNDROME	9	1	5.38	9.61	1.22	75.86	8	1	4.41	8.55	1.07	68.37
ECHOCARDIOGRAM ABNORMAL	10	2	4.56	5.34	1.17	24.37	10	2	4.57	5.34	1.17	24.39
LOW DENSITY LIPOPROTEIN INCREASED	10	2	4.56	5.34	1.17	24.37	10	2	4.57	5.34	1.17	24.39
PERICARDIAL DISEASE	10	2	4.56	5.34	1.17	24.37	10	2	4.57	5.34	1.17	24.39
ANGLE CLOSURE GLAUCOMA	8	1	4.41	8.54	1.07	68.31	8	1	4.41	8.55	1.07	68.37
NEOPLASM PROGRESSION	8	1	4.41	8.54	1.07	68.31	8	1	4.41	8.55	1.07	68.37
POIKILOCYTOSIS	8	1	4.41	8.54	1.07	68.31	8	1	4.41	8.55	1.07	68.37
RED CELL DISTRIBUTION WIDTH INCREASED	8	1	4.41	8.54	1.07	68.31	8	1	4.41	8.55	1.07	68.37

SALIVARY GLAND MASS	8	1	4.41	8.54	1.07	68.31	8	1	4.41	8.55	1.07	68.37
SCIATIC NERVE INJURY	8	1	4.41	8.54	1.07	68.31	8	1	4.41	8.55	1.07	68.37
VIRAL PITYRIASIS	8	1	4.41	8.54	1.07	68.31	8	1	4.41	8.55	1.07	68.37
COLLECTOMY	39	21	6.01	1.98	1.17	3.37	37	18	7.16	2.20	1.25	3.86
PRONE POSITION	33	18	4.82	1.96	1.10	3.48	34	18	5.39	2.02	1.14	3.57
ELECTROCARDIOGRAM QT	34	19	4.68	1.91	1.09	3.35	33	17	5.56	2.07	1.16	3.72
PROLONGED	15	6	3.60	2.67	1.04	6.88	13	4	4.32	3.47	1.13	10.65
ILFOSOMY	20	10	3.33	2.14	1.00	4.56	20	8	5.09	2.67	1.18	6.07
SOMNAMBULISM	19	10	2.77	2.03	0.94	4.36	19	8	4.40	2.54	1.11	5.80
SPINAL FUSION SURGERY	10	3	3.18	3.56	0.98	12.93	10	2	4.57	5.34	1.17	24.39
EYELID CONTUSION	10	3	3.18	3.56	0.98	12.93	10	2	4.57	5.34	1.17	24.39
ROTATOR CUFF REPAIR	6	1	2.56	6.41	0.77	53.22	6	0				

PREFERRED Medical Dictionary for Regulatory Activities (MedDRA) Terms (VAERS-1 Box 7, VAERS 2.0 Box 18)

For Current Week and Past Week Comparison

Following ALL 12/14/2020-04/08/2022 COVID19 Pfizer Ages 18+ Vaccines

Compared to ALL 12/14/2020-04/08/2022 COVID19 Moderna Ages 18+ Vaccines

SERIOUS AGES 18+ YEARS, Initial domestic reports only, VAERS reports as of 04/08/2022

Vaccination, Received, and Completed Date: 12/14 - 04/08 (Current Week) and 12/14 - 04/01 (Past Week)

N>=3 (Current Week), PRR=2.00 (Ratio of Proportions), Chi-Square=4.00

MedDRA PT's sorting based on lower confidence limit and PFIZER adverse event count from 12/14/2020-04/08/2022

SERIOUS AGES 18+ YEARS excludes missing ages

MedDRA Codes ALL Reports (SERIOUS 18+)	12/14/2020- 04/08/2022 PFIZER N=36603	12/14/2020- 04/08/2022 MODERNA N=29929	12/14-04/08 Chi-Square	12/14-04/08 PRR	12/14-04/08 LCL	12/14-04/08 UCL	12/14/2020- 04/01/2022 PFIZER N=36199	12/14/2020- 04/01/2022 MODERNA N=29626	12/14-04/01 Chi-Square	12/14-04/01 PRR	12/14-04/01 LCL	12/14-04/01 UCL
IMMUNISATION	130	8	84.23	13.29	6.51	27.13	130	8	84.22	13.30	6.51	27.15
VACCINATION FAILURE	65	6	36.87	8.86	3.84	20.44	64	5	38.28	10.48	4.22	26.02
APPARENT LIFE-THREATENING EVENT	61	7	31.71	7.13	3.26	15.57	61	7	31.75	7.13	3.26	15.59
DRUG INEFFECTIVE	108	25	35.88	3.53	2.39	5.46	106	25	34.60	3.47	2.24	5.36
WHITE BLOOD CELL COUNT INCREASED	46	8	18.68	4.70	2.22	9.96	45	8	17.99	4.60	2.17	9.76
DISEASE RECURRENCE	33	5	14.30	5.40	2.11	13.82	33	5	14.32	5.40	2.11	13.83
VIBRATORY SENSE INCREASED	24	3	11.19	6.54	1.97	21.72	23	3	10.46	6.27	1.88	20.90
OFF LABEL USE	74	21	19.21	2.88	1.78	4.68	74	21	19.24	2.88	1.78	4.68
EATING DISORDER	44	12	11.63	3.00	1.58	5.68	43	12	11.04	2.93	1.55	5.56
OSTEOPORESIA	27	7	7.22	3.15	1.37	7.24	27	7	7.24	3.16	1.37	7.25
NEAR DEATH EXPERIENCE	47	16	9.00	2.40	1.36	4.33	46	16	8.48	2.35	1.33	4.16
PERITONITIS	31	9	7.29	2.82	1.34	5.91	31	9	7.31	2.82	1.34	5.92
BLOOD CHOLESTEROL INCREASED	24	6	6.59	3.27	1.34	8.00	24	6	6.61	3.27	1.34	8.01
VERTEBRAL ARTERY DISSECTION	16	3	5.43	4.36	1.27	14.96	16	3	5.43	4.36	1.27	14.98
PHOTOSENSITIVITY REACTION	25	7	6.01	2.92	1.26	6.75	24	7	5.43	2.81	1.21	6.51
NORMAL LABOUR	33	11	6.32	2.45	1.24	4.85	26	9	4.52	2.36	1.11	5.04
PNEUMONIA PSEUDOMONAL	15	3	4.75	4.09	1.18	14.12	14	3	3.82	3.82	1.10	13.39
VEN DISORDER	15	3	4.75	4.09	1.18	14.12	14	3	4.10	3.82	1.10	13.39
VIRAL SEPSIS	17	4	4.71	3.48	1.17	10.33	17	4	4.72	3.48	1.17	10.34
MUSCLE FATIGUE	33	12	5.39	2.25	1.16	4.35	32	11	5.80	2.38	1.20	4.72
RENAL TRANSPLANT	21	6	4.77	2.86	1.16	7.09	21	6	4.78	2.86	1.16	7.10
MAST CELL ACTIVATION SYNDROME	19	5	4.72	3.11	1.16	8.32	19	5	4.73	3.11	1.16	8.33
BASAL GANGLIA INFARCTION	27	9	5.03	2.45	1.15	5.22	27	9	5.04	2.46	1.15	5.22
BREAST CANCER FEMALE	30	11	4.75	2.23	1.12	4.45	30	11	4.77	2.23	1.12	4.45
BLOOD DISORDER	24	8	4.39	2.45	1.10	5.46	24	8	4.40	2.46	1.10	5.46
SALIVARY HYPERSCRETION	22	7	4.29	2.57	1.10	6.01	22	7	4.30	2.57	1.10	6.02
FACIAL SPASM	14	3	4.09	3.82	1.10	13.28	14	3	4.10	3.82	1.10	13.29
DECREASED NASAL ABIAL FOLD	20	6	4.20	2.73	1.09	6.79	20	6	4.21	2.73	1.10	6.79
ENDOTRACHEAL INTUBATION COMPLICATION	16	4	4.09	3.27	1.09	9.78	16	4	4.09	3.27	1.09	9.79
VOCAL CORD PARALYSIS	16	4	4.09	3.27	1.09	9.78	16	4	4.09	3.27	1.09	9.79
MOANING	64	26	8.79	2.01	1.28	3.17	63	26	8.35	1.98	1.26	3.13
PHOTOPSIA	47	19	6.36	2.02	1.19	3.45	46	19	5.92	1.98	1.16	3.38
AUTONOMIC NERVOUS SYSTEM IMBALANCE	42	17	5.60	2.02	1.15	3.55	41	17	5.16	1.97	1.12	3.47
PRODUCT USE ISSUE	28	2	16.29	11.45	2.73	48.05	28	2	16.31	11.46	2.73	48.09
LIVE BIRTH	21	2	10.82	8.59	2.01	36.61	21	2	10.83	8.59	2.02	36.65

MENISCUS INJURY	14	1	7.43	11.45	1.51	87.05	14	1	7.43	11.46	1.51	87.13
PNEUMOTHORAX	16	2	7.03	6.54	1.50	28.45	15	2	6.31	6.14	1.40	26.84
SPONTANEOUS	13	1	6.65	10.63	1.39	81.25	13	1	6.65	10.64	1.39	81.33
ELDERLY	12	2	4.16	4.91	1.10	21.92	12	2	4.17	4.91	1.10	21.94
BODY TEMPERATURE	12	2	4.16	4.91	1.10	21.92	12	2	4.17	4.91	1.10	21.94
FLUCTUATION	10	1	4.37	8.18	1.05	63.87	10	1	4.37	8.18	1.05	63.93
ENTEROBACTER INFECTION	66	27	8.94	2.00	1.28	3.13	64	26	8.82	2.01	1.28	3.18
POSTURAL ORTHOSTATIC	26	10	3.64	2.13	1.03	4.41	26	9	4.52	2.56	1.11	5.04
TACHYCARDIA SYNDROME	37	17	3.45	1.78	1.00	3.16	35	14	4.71	2.05	1.10	3.80
HEPATIC MASS	27	11	3.33	2.01	1.00	4.05	27	10	4.14	2.21	1.07	4.56
COLECTOMY	30	13	3.21	1.89	0.98	3.62	30	11	4.77	2.23	1.12	4.45
MASTICATION DISORDER	16	6	2.12	2.18	0.85	5.57	16	4	4.09	3.27	1.09	9.79
QUALITY OF LIFE DECREASED	8	1	2.92	6.54	0.82	52.30	8	0	-	-	-	-
SPINAL FUSION SURGERY	8	1	2.92	6.54	0.82	52.30	8	0	-	-	-	-
ALLERGY TO CHEMICALS	5	1	0.97	4.09	0.48	34.99	5	0	-	-	-	-
BONE DISORDER	5	1	0.97	4.09	0.48	34.99	5	0	-	-	-	-
INTUSSUSCEPTION	5	1	0.97	4.09	0.48	34.99	5	0	-	-	-	-