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Search the U.S. Government's VAERS Data

Welcome to the VAERS *Wayback Machine*

Each month (or lately, each week), the U.S. Government publishes a new release of its VAERS database. Most of the differences between releases consist of new VAERS cases that were introduced since the previous release. But the government never closes a VAERS case, and may make changes to any case at any time. Sometimes cases are even deleted.

The VAERS *Wayback Machine* has a collection of old releases of the VAERS database, starting in 2003. It allows you to examine the government data more carefully and observe how the data changes over time. Here are some of the things that you can do with the VAERS Wayback Machine:

Follow Changes to a VAERS Case

Enter a VAERS ID number here to see all changes that have been made to that case since it was first released. You can find out when the case first appeared, how it was modified, and if applicable, when it was deleted. See the **How Differences are Shown** section below for more about interpreting the results.

VAERS ID:

Follow

History of Changes from the VAERS *Wayback Machine*

First Appeared on 7/23/2021

VAERS ID: 1315556

VAERS Form: 2

Age:

Sex: Female

Location: Foreign

Vaccinated: 2021-03-28

Onset: 0000-00-00

Submitted: 0000-00-00

Entered: 2021-05-13

Vaccination / Manufacturer (1 vaccine)	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA	- / 1	- / OT

Administered by: Unknown **Purchased by:** ??

Symptoms: Condition aggravated, Chronic inflammatory demyelinating polyradiculoneuropathy

Life Threatening? No

Birth Defect? No

Died? No

Permanent Disability? No

Recovered? No

Office Visit (V2.0)? No

ER or Office Visit (V1.0)? No

ER or ED Visit (V2.0)? No

Hospitalized? Yes, days: (blank)

Extended hospital stay? No

Previous Vaccinations:

Other Medications: COTRIMOXAZOLE; PROGRAFT; CELLCEPT [MYCOPHENOLATE MOFETIL]; PANTOPRAZOLE; CALCIUM CARBONATE W/VITAMIN D [CALCIUM CARBONATE;COLECALCIFEROL]

Current Illness: CIDP; Guillain Barre syndrome

Preexisting Conditions:

Allergies:

Diagnostic Lab Data:

CDC 'Split Type': NLMODERNATX, INC.MOD20211

Write-up: (Exacerbation) CIDP; (Exacerbation) CIDP; This regulatory authority case was reported by a physician (subsequently medically confirmed) and describes the occurrence of CHRONIC INFLAMMATORY DEMYELINATING POLYRADICULONEUROPATHY ((Exacerbation) CIDP) in a female patient of an

unknown age who received mRNA-1273 (COVID 19 Vaccine Moderna) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Concurrent medical conditions included CIDP and Guillain Barre syndrome. Concomitant products included SULFAMETHOXAZOLE, TRIMETHOPRIM (COTRIMOXAZOLE), TACROLIMUS (PROGRAFT), MYCOPHENOLATE MOFETIL (CELLCEPT [MYCOPHENOLATE MOFETIL]), PANTOPRAZOLE and CALCIUM CARBONATE, COLECALCIFEROL (CALCIUM CARBONATE W/VITAMIN D [CALCIUM CARBONATE;COLECALCIFEROL]) for an unknown indication. On 28-Mar-2021, the patient received first dose of mRNA-1273 (COVID 19 Vaccine Moderna) (unknown route) 1 dosage form. On an unknown date, the patient experienced CHRONIC INFLAMMATORY DEMYELINATING POLYRADICULONEUROPATHY ((Exacerbation) CIDP) (seriousness criterion hospitalization) and CONDITION AGGRAVATED ((Exacerbation) CIDP). At the time of the report, CHRONIC INFLAMMATORY DEMYELINATING POLYRADICULONEUROPATHY ((Exacerbation) CIDP) and CONDITION AGGRAVATED ((Exacerbation) CIDP) had not resolved. The action taken with mRNA-1273 (COVID 19 Vaccine Moderna) (Unknown) was unknown. For mRNA-1273 (COVID 19 Vaccine Moderna) (Unknown), the reporter did not provide any causality assessments. No treatment information was provided. Company comment: Very limited information regarding the event onset date has been provided at this time. No follow up is possible. A causal relationship cannot be excluded. Most recent FOLLOW-UP information incorporated above includes: On 30-Apr-2021: No new information.; Sender's Comments: Very limited information regarding the event onset date has been provided at this time. No follow up is possible. A causal relationship cannot be excluded.

Record is removed as of 7/8/2022

First Appeared on 9/17/2021

VAERS ID: 1576921

VAERS Form: 2

Age:

Sex: Female

Location: Foreign

Vaccinated: 2021-06-10

Onset: 2021-06-11

Submitted: 0000-00-00

Entered: 2021-08-17

Vaccination / Manufacturer (1 vaccine)	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	FC3143 / 1	- / -

Administered by: Other **Purchased by:** ??

Symptoms: Lumbar puncture, Multiple sclerosis, CSF test, Scan, Blood test, Relapsing-remitting multiple sclerosis, Magnetic resonance imaging

Life Threatening? No

Birth Defect? No

Died? No

Permanent Disability? No

Recovered? No

Office Visit (V2.0)? Yes

ER or Office Visit (V1.0)? No

ER or ED Visit (V2.0)? No

Hospitalized? No

Previous Vaccinations:

Other Medications:

Current Illness:

Preexisting Conditions: Comments: List of non-encoded Patient Relevant History:

Patient Other Relevant History 1: none

Allergies:

Diagnostic Lab Data: Test Name: Blood test; Result Unstructured Data: Test Result:results unknown; Test Name: CSF; Result Unstructured Data: Test Result:oligoclonal bands in CSF; Test Name: Lumbar puncture; Result Unstructured Data: Test Result:results unknown; Test Name: MRI; Result Unstructured Data: Test Result:results unknown; Test Name: radiography; Result Unstructured Data: Test Result:radiographic dissemination in space

CDC 'Split Type': NLPFIZER INC202100990675

Write-up: Start attack of multiple sclerosis (not previously known with multiple sclerosis); Start attack of multiple sclerosis (not previously known with multiple sclerosis); This is a spontaneous report received from a contactable consumer (patient)

downloaded from the regulatory authority (regulatory authority number NL-LRB-00623622, Safety Report Unique Identifier NL-LRB-00645931). A 52 years old female patient received BNT162B2 (COMIRNATY; lot FC3143) on 10Jun2021, as the first single dose, for COVID-19 immunisation. The patient did not have a history of multiple sclerosis, neither did she have any other medical history or recent infection. Concomitant medications were none. On 11Jun2021 the patient experienced start attack of multiple sclerosis (not previously known with multiple sclerosis) with relapsing remitting multiple sclerosis following administration of Comirnaty. The events were reported serious as other medically important condition. MRI, lumbar puncture and blood test were performed (results not reported), after which multiple sclerosis was diagnosed. It started with tingling feet and progressed towards tingling hands, numbness in breasts and abdomen and a band-like sensation beneath her breast. She had decreased control over urination and defecation. Conclusion: relapsing remitting multiple sclerosis according to the 2017 McDonald criteria (clinically transverse myelitis, radiographic dissemination in space, oligoclonal bands in CSF). Reporter comment: BioNTech/Pfizer vaccine (Comirnaty). Past drug therapy BioNTech/Pfizer vaccine (Comirnaty): no. Start attack of multiple sclerosis (not previously known with multiple sclerosis). Additional information ADR: First neurological complaints within 24 hours after the vaccine confounding factors: afterwards multiple sclerosis research. COVID-19: Previous COVID-19 infection: No. Other: diagnostic procedures: MRI, spinal tap, blood test. Sender's Comments: Since Multiple Sclerosis is listed in the list, the reaction is considered as serious by the regulatory authority. Additional information ADR: Follow up 29Jul2021: 1. Tingling feet within 24 hours, then quickly tingling hands, numbness in breasts and abdomen. Little control of urine and stool. Band feeling under the chest. 2. Little change. Lost feeling of feeling after prednisone and regain control of urine and stool. 3. After the examinations she was diagnosed with MS. From the outpatient update letter of the neurology department: patient visited the neurology outpatient clinic on 25Jun2021. Reason for coming/referral. Results of additional examination in rapidly progressive sensory complaints of arms, trunk, and legs with anamnestic also numbness in the riding breeches area and reduced sensation of passing stools. Conclusion: Relapsing remitting multiple sclerosis according to the 2017 criteria. Policy: Diagnosis and treatment options discussed. policy determined. The patient received oral methylprednisone treatment from 23Jun2021 to 25Jun2021. Short term nurse appointment. The patient had not recovered from relapsing remitting multiple sclerosis 1.5 month after onset. No follow-up attempts are possible. No further information is expected.; Reporter's Comments: BioNTech/Pfizer vaccine (Comirnaty). Past drug therapy BioNTech/Pfizer vaccine (Comirnaty): no. Start attack of multiple sclerosis (not previously known with multiple sclerosis). Additional information ADR: First neurological complaints within 24 hours after the vaccine confounding factors: afterwards multiple sclerosis research. COVID-19: Previous COVID-19 infection: No. Other: diagnostic procedures: MRI, spinal tap, blood test.

Record is removed as of 8/19/2022

First Appeared on 10/1/2021

VAERS ID: 1669124

VAERS Form: 2

Age:

Sex: Female

Location: Foreign

Vaccinated: 2021-04-06

Onset: 2021-04-07

Submitted: 0000-00-00

Entered: 2021-09-03

Vaccination / Manufacturer (1 vaccine)	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	- / 1	- / -

Administered by: Other **Purchased by:** ??

Symptoms: Dyspnoea, Fatigue, Influenza like illness

Life Threatening? No

Birth Defect? No

Died? No

Permanent Disability? No

Recovered? No

Office Visit (V2.0)? No

ER or Office Visit (V1.0)? No

ER or ED Visit (V2.0)? No

Hospitalized? Yes, days: (blank)

Extended hospital stay? No

Previous Vaccinations:

Other Medications:

Current Illness:

Preexisting Conditions: Medical History/Concurrent Conditions: Increased blood sugar; heart disorder (uses medications for her heart).

Allergies:

Diagnostic Lab Data:

CDC 'Split Type': NLPFIZER INC202101080918

Write-up: This is a spontaneous report from a contactable consumer (patient). An approximately 73-year-old female patient received the first dose of BNT162B2 (Comirnaty; solution for injection), via an unspecified route of administration, on Apr 6, 2021, single dose, for COVID-19 immunization. Medical history included heart disorder (uses medications for her heart) and blood sugar level going up very fast. Concomitant

medications included unspecified medications for heart. On Apr 7, 2021, patient experienced flu-like feeling. On Apr 8, 2021, patient experienced shortness of breath, which caused hospitalization on Apr 9, 2021. On an unspecified date, patient got tired quickly. The outcome of the events: unknown. The lot number for the vaccine, BNT162B2, not provided and will be requested during follow-up.

Record is removed as of 10/7/2022

First Appeared on 10/1/2021

VAERS ID: 1671947

VAERS Form: 2

Age: 49.0

Sex: Female

Location: Foreign

Vaccinated: 2021-07-07

Onset: 2021-07-07

Submitted: 0000-00-00

Entered: 2021-09-04

Vaccination / Manufacturer (1 vaccine)	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA	3003186 / UNK	- / OT

Administered by: Unknown **Purchased by:** ??

Symptoms: Arthralgia, Chills, Dyspepsia, Fatigue, Headache, Injection site inflammation, Injection site pain, Intestinal obstruction, Malaise, Myalgia, Nausea

Life Threatening? No

Birth Defect? No

Died? No

Permanent Disability? No

Recovered? No

Office Visit (V2.0)? No

ER or Office Visit (V1.0)? No

ER or ED Visit (V2.0)? No

Hospitalized? No

Previous Vaccinations:

Other Medications: SPIRONOLACTON; METOPROLOL; LOSARTAN

Current Illness: Hypertension

Preexisting Conditions:

Allergies:

Diagnostic Lab Data:

CDC 'Split Type': NLMODERNATX, INC.MOD20213

Write-up: This case was received via regulatory authority (Reference number: NL-EMA-DD-20210823-banala_s-154306) on 27-Aug-2021 and was forwarded to Moderna on 27-Aug-2021. This regulatory authority case was reported by a consumer and describes the occurrence of INTESTINAL OBSTRUCTION in a 49-year-old female patient who received mRNA-1273 (Spikevax) (batch nos. 3002338 and 3003186) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed

below. Concurrent medical conditions included Hypertension. Concomitant products included METOPROLOL from 15-Apr-2015 to an unknown date for Hypertension, SPIRONOLACTONE (SPIRONOLACTON) from 15-Apr-2015 to an unknown date and LOSARTAN from 01-Sep-2015 to an unknown date for an unknown indication. On 07-Jul-2021, the patient received dose of mRNA-1273 (Spikevax) (unknown route) dosage was changed to .5 milliliter. On an unknown date, the patient received dose of mRNA-1273 (Spikevax) (unknown route) .5 milliliter. On 07-Jul-2021, the patient experienced the first episode of MALAISE, the first episode of MYALGIA, the first episode of CHILLS, the first episode of HEADACHE, ARTHRALGIA and INJECTION SITE PAIN. On 08-Jul-2021, the patient experienced DYSPEPSIA and NAUSEA. On 10-Jul-2021, the patient experienced INTESTINAL OBSTRUCTION (seriousness criterion medically significant). On an unknown date, the patient experienced the second episode of MALAISE, INJECTION SITE INFLAMMATION, the second episode of MYALGIA, the second episode of HEADACHE, FATIGUE and the second episode of CHILLS. On 09-Jul-2021, ARTHRALGIA had resolved. On 10-Jul-2021, INTESTINAL OBSTRUCTION, INJECTION SITE PAIN and NAUSEA had resolved. At the time of the report, DYSPEPSIA was resolving and last episode of MALAISE, INJECTION SITE INFLAMMATION, the last episode of MYALGIA, the last episode of HEADACHE, FATIGUE and the last episode of CHILLS had resolved. No treatment medications were reported. Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.; Sender's Comments: Based on the current available information and temporal association between the use of the product and the start date of the events, a causal relationship cannot be excluded.

Record is removed as of 5/6/2022

First Appeared on 12/17/2021

VAERS ID: 1953817

VAERS Form: 2

Age:

Sex: Male

Location: Foreign

Vaccinated: 0000-00-00

Onset: 0000-00-00

Submitted: 0000-00-00

Entered: 2021-12-16

Vaccination / Manufacturer (1 vaccine)	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	- / UNK	- / -

Administered by: Other **Purchased by:** ??

Symptoms: Alopecia

Life Threatening? No

Birth Defect? No

Died? No

Permanent Disability? No

Recovered? No

Office Visit (V2.0)? No

ER or Office Visit (V1.0)? No

ER or ED Visit (V2.0)? No

Hospitalized? No

Previous Vaccinations:

Other Medications:

Current Illness:

Preexisting Conditions:

Allergies:

Diagnostic Lab Data:

CDC 'Split Type': NLPFIZER INC202101717629

Write-up: Extreme hair loss (90% so far); This is a spontaneous report received from a contactable reporter(s) (Physician). A male patient received bnt162b2 (COMIRNATY) (Batch/Lot number: unknown) as dose number unknown, single for covid-19 immunisation. The patient's relevant medical history and concomitant medications were not reported. The following information was reported: ALOPECIA (medically significant), outcome "unknown", described as "Extreme hair loss (90% so far)". The lot number for bnt162b2 was not provided and will be requested during follow up.; Sender's

Comments: Based on the information in the case report and a plausible temporal relationship, a possible causal relationship between the event Alopecia and suspect drug BNT162B2 cannot be excluded. The impact of this report on the benefit/risk profile of the Pfizer product is evaluated as part of Pfizer procedures for safety evaluation, including the review and analysis of aggregate data for adverse events. Any safety concern identified as part of this review, as well as any appropriate action in response, will be promptly notified to regulatory authorities, Ethics Committees, and Investigators, as appropriate.

Record is removed as of 6/17/2022

First Appeared on 1/14/2022

VAERS ID: 2013389

VAERS Form: 2

Age: 27.0

Sex: Female

Location: Foreign

Vaccinated: 2021-08-11

Onset: 2021-08-11

Submitted: 0000-00-00

Entered: 2022-01-07

Vaccination / Manufacturer (1 vaccine)	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA	3004493 / UNK	- / OT

Administered by: Unknown **Purchased by:** ??

Symptoms: Brain abscess, Headache

Life Threatening? Yes

Birth Defect? No

Died? No

Permanent Disability? No

Recovered? No

Office Visit (V2.0)? No

ER or Office Visit (V1.0)? No

ER or ED Visit (V2.0)? No

Hospitalized? Yes, days: (blank)

Extended hospital stay? No

Previous Vaccinations:

Other Medications:

Current Illness:

Preexisting Conditions:

Allergies:

Diagnostic Lab Data:

CDC 'Split Type': NLMODERNATX, INC.MOD20214

Write-up: Right pre-central brain abscess; Headache; This case was received via regulatory authority (Reference number: NL-LRB-00720087) on 22-Dec-2021 and was forwarded to Moderna on 22-Dec-2021. This regulatory authority case was reported by a consumer and describes the occurrence of BRAIN ABSCESS (Right pre-central brain abscess) in a 27-year-old female patient who received mRNA-1273 (Spikevax) (batch no. 3004493) for COVID-19 vaccination. The occurrence of additional non-serious

events is detailed below. Previously administered products included for Drug use for unknown indication: COVID-19 VACCINE MODERNA on 07-Jul-2021. Past adverse reactions to the above products included Injection site allergic reaction with COVID-19 VACCINE MODERNA. On 11-Aug-2021, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 11-Aug-2021, the patient experienced HEADACHE (Headache) and BRAIN ABSCESS (Right pre-central brain abscess) (seriousness criteria hospitalization, medically significant and life threatening). At the time of the report, HEADACHE (Headache) had not resolved and BRAIN ABSCESS (Right pre-central brain abscess) was resolving. No concomitant medications were reported. No Treatment medications were reported. Patient was experienced Right brain abscess pre-central. Company Comment: This case concerns a 27-year-old female subject, with no medical history reported, who experienced the unexpected and serious event of Brain abscess. The event occurred the same day after an unknown dose of mRNA-1273 vaccine. The rechallenge is not applicable, as it cannot be assessed. Previous dose of mRNA-1273 vaccine was reported. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 22-Dec-2021: Translation document received on 24-DEC-2021 contain Event Verbatim updated.; Sender's Comments: This case concerns a 27-year-old female subject, with no medical history reported, who experienced the unexpected and serious event of Brain abscess. The event occurred the same day after an unknown dose of mRNA-1273 vaccine. The rechallenge is not applicable, as it cannot be assessed. Previous dose of mRNA-1273 vaccine was reported. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.

Record is removed as of 4/29/2022

First Appeared on 1/14/2022

VAERS ID: 2013390

VAERS Form: 2

Age: 34.0

Sex: Female

Location: Foreign

Vaccinated: 2021-07-25

Onset: 2021-07-26

Submitted: 0000-00-00

Entered: 2022-01-07

Vaccination / Manufacturer (1 vaccine)	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA	3003659 / UNK	- / OT

Administered by: Unknown **Purchased by:** ??

Symptoms: Condition aggravated, Post-acute COVID-19 syndrome

Life Threatening? No

Birth Defect? No

Died? No

Permanent Disability? Yes

Recovered? No

Office Visit (V2.0)? No

ER or Office Visit (V1.0)? No

ER or ED Visit (V2.0)? No

Hospitalized? No

Previous Vaccinations:

Other Medications: PYRIDOSTIGMINE; IVABRADINE KRKA; FLUDROCORTISON

Current Illness:

Preexisting Conditions: Medical History/Concurrent Conditions: Long COVID; Suspected COVID-19

Allergies:

Diagnostic Lab Data:

CDC 'Split Type': NLMODERNATX, INC.MOD20214

Write-up: I have long covid and this is greatly aggravated after the second vaccination. I have deteriorated permanently; I have long covid and this is greatly aggravated after the second vaccination. I have deteriorated permanently; This case was received via Regulatory Authority (Reference number: NL-LRB-00720238) on 22-Dec-2021 and was forwarded to Moderna on 22-Dec-2021. This regulatory authority case was reported by a consumer and describes the occurrence of POST-ACUTE COVID-19 SYNDROME (I

have long covid and this is greatly aggravated after the second vaccination. I have deteriorated permanently) and CONDITION AGGRAVATED (I have long covid and this is greatly aggravated after the second vaccination. I have deteriorated permanently) in a 34-year-old female patient who received mRNA-1273 (Spike-vax) (batch no. 3003659) for COVID-19 vaccination. The patient's past medical history included Long COVID and Suspected COVID-19 on 06-Apr-2020. Previously administered products included for Product used for unknown indication: Moderna vaccin (Spikevax) COVID-19 VACCIN MODERNA INJVLST 0 and5ML on 06-Jun-2021. Past adverse reactions to the above products included No adverse event with Moderna vaccin (Spikevax) COVID-19 VACCIN MODERNA INJVLST 0 and5ML. Concomitant products included PYRIDOSTIGMINE, IVABRADINE HYDROCHLORIDE (IVABRADINE KRKA) and FLUDROCORTISONE ACETATE (FLUDROCORTISON) for an unknown indication. On 25-Jul-2021, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 26-Jul-2021, the patient experienced POST-ACUTE COVID-19 SYNDROME (I have long covid and this is greatly aggravated after the second vaccination. I have deteriorated permanently) (seriousness criterion disability) and CONDITION AGGRAVATED (I have long covid and this is greatly aggravated after the second vaccination. I have deteriorated permanently) (seriousness criterion disability). At the time of the report, POST-ACUTE COVID-19 SYNDROME (I have long covid and this is greatly aggravated after the second vaccination. I have deteriorated permanently) and CONDITION AGGRAVATED (I have long covid and this is greatly aggravated after the second vaccination. I have deteriorated permanently) had not resolved. Treatment medications was not provided by the reporter. Company comment: This regulatory case concerns a 34-year-old, female patient with medical history of long COVID and suspected COVID-19, who experienced the unexpected, serious (disabling) and AESI of post-acute COVID-19 syndrome, among others. The event occurred 1 day after receiving an unknown dose number of mRNA-1273 vaccine. The rechallenge is not applicable. The medical history of long COVID and suspected COVID-19 remain as confounders. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.; Sender's Comments: This regulatory case concerns a 34-year-old, female patient with medical history of long COVID and suspected COVID-19, who experienced the unexpected, serious (disabling) and AESI of post-acute COVID-19 syndrome, among others. The event occurred 1 day after receiving an unknown dose number of mRNA-1273 vaccine. The rechallenge is not applicable. The medical history of long COVID and suspected COVID-19 remain as confounders. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.

Record is removed as of 4/29/2022

First Appeared on 1/14/2022

VAERS ID: 2013392

VAERS Form: 2

Age: 52.0

Sex: Male

Location: Foreign

Vaccinated: 2021-06-18

Onset: 2021-06-21

Submitted: 0000-00-00

Entered: 2022-01-07

Vaccination / Manufacturer (1 vaccine)	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA	3002537 / 1	- / OT

Administered by: Unknown **Purchased by:** ??

Symptoms: Arthralgia, Atrial flutter, Dyspnoea, Fatigue, Malaise, Myalgia, Palpitations

Life Threatening? No

Birth Defect? No

Died? No

Permanent Disability? No

Recovered? No

Office Visit (V2.0)? No

ER or Office Visit (V1.0)? No

ER or ED Visit (V2.0)? No

Hospitalized? Yes, days: (blank)

Extended hospital stay? No

Previous Vaccinations:

Other Medications: VALSARTAN/HYDROCHLOORTHIAZIDE; SIMVASTATINE

Current Illness:

Preexisting Conditions: Medical History/Concurrent Conditions: Atrial flutter (2000 blossom flutter. Then this went back to sinus rhythm by itself within a number of days. Never had it again until June 2021.); Hypercholesterolaemia; Hypertension

Allergies:

Diagnostic Lab Data:

CDC 'Split Type': NLMODERNATX, INC.MOD20214

Write-up: Heart rhythm disorder (atrium flutter); Accompanied by shortness of breath and palpitations.; Accompanied by shortness of breath and palpitations.; Muscle pain; Fatigue; Joint pain; Don't feel good; This case was initially received Reference number: NL-LRB-00720773) on 22-Dec-2021. The most recent information was received on 27-

Dec-2021 and was forwarded to Moderna on 27-Dec-2021. This regulatory authority case was reported by a consumer and describes the occurrence of ATRIAL FLUTTER (Heart rhythm disorder (atrium flutter)), PALPITATIONS (Accompanied by shortness of breath and palpitations.) and DYSPNOEA (Accompanied by shortness of breath and palpitations.) in a 52-year-old male patient who received mRNA-1273 (Spikevax) (batch no. 3002537) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. The patient's past medical history included Hypertension, Hypercholesterolaemia and Atrial flutter (2000 blossom flutter. Then this went back to sinus rhythm by itself within a number of days. Never had it again until June 2021.) in 2000. Concomitant products included HYDROCHLOROTHIAZIDE, VALSARTAN (VALSARTAN/HYDROCHLOROTHIAZIDE) and SIMVASTATINE for an unknown indication. On 18-Jun-2021, the patient received first dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 21-Jun-2021, the patient experienced ATRIAL FLUTTER (Heart rhythm disorder (atrium flutter)) (seriousness criteria hospitalization and medically significant), PALPITATIONS (Accompanied by shortness of breath and palpitations.) (seriousness criteria hospitalization and medically significant), DYSPNOEA (Accompanied by shortness of breath and palpitations.) (seriousness criteria hospitalization and medically significant), MYALGIA (Muscle pain), FATIGUE (Fatigue), ARTHRALGIA (Joint pain) and MALAISE (Don't feel good). On 25-Jun-2021, MYALGIA (Muscle pain) and ARTHRALGIA (Joint pain) had resolved. At the time of the report, ATRIAL FLUTTER (Heart rhythm disorder (atrium flutter)), PALPITATIONS (Accompanied by shortness of breath and palpitations.), DYSPNOEA (Accompanied by shortness of breath and palpitations.) and FATIGUE (Fatigue) was resolving and MALAISE (Don't feel good) had resolved. No treatment medications were provided. Company comment: This is a regulatory authority case concerning a 52-year-old male patient with medical history of hypertension and atrial flutter in 2000 (went back to sinus rhythm by itself within a number of days. Never had it again until June 2021), who experienced unexpected events of atrial flutter, dyspnoea and palpitations (seriousness criteria hospitalization and medically significant). The events occurred 3 days after the first dose of mRNA-1273 vaccine. Clinical course, diagnostic tests results and treatment details were not provided. Medical history of hypertension and atrial flutter remain confounders. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 27-Dec-2021: Significant follow up - medical history added; Sender's Comments: This is a regulatory authority case concerning a 52-year-old male patient with medical history of hypertension and atrial flutter in 2000 (went back to sinus rhythm by itself within a number of days. Never had it again until June 2021), who experienced unexpected events of atrial flutter, dyspnoea and palpitations (seriousness criteria hospitalization and medically significant). The events occurred 3 days after the first dose of mRNA-1273 vaccine. Clinical course, diagnostic tests results and treatment details were not provided. Medical history of hypertension and atrial flutter remain confounders. The benefit-risk relationship of mRNA-1273 vaccine is not affected by this report.

Record is removed as of 7/15/2022

First Appeared on 1/14/2022

VAERS ID: 2013393

VAERS Form: 2

Age: 43.0

Sex: Male

Location: Foreign

Vaccinated: 2021-07-12

Onset: 2021-10-07

Submitted: 0000-00-00

Entered: 2022-01-07

Vaccination / Manufacturer (1 vaccine)	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA	LOT3003652 / UNK	- / OT

Administered by: Unknown **Purchased by:** ??

Symptoms: Atrial fibrillation, Lymphoma, Pericarditis

Life Threatening? No

Birth Defect? No

Died? No

Permanent Disability? No

Recovered? Yes

Office Visit (V2.0)? No

ER or Office Visit (V1.0)? No

ER or ED Visit (V2.0)? No

Hospitalized? Yes, days: (blank)

Extended hospital stay? No

Previous Vaccinations:

Other Medications:

Current Illness:

Preexisting Conditions:

Allergies:

Diagnostic Lab Data:

CDC 'Split Type': NLMODERNATX, INC.MOD20214

Write-up: inflamed pericardium; atrial fibrillation; lymphoma; This regulatory authority case was reported by a consumer and describes the occurrence of PERICARDITIS (inflamed pericardium) in a 43-year-old male patient who received mRNA-1273 (Spikevax) (batch no. LOT3003652) for COVID-19 vaccination. The occurrence of additional non-serious events is detailed below. Previously administered products included for Product used for unknown indication: SPIKEVAX on 07-Jun-2021. Past

adverse reactions to the above products included No adverse event with SPIKEVAX. On 12-Jul-2021, the patient received dose of mRNA-1273 (Spikevax) (unknown route) 1 dosage form. On 07-Oct-2021, the patient experienced PERICARDITIS (inflamed pericardium) (seriousness criterion hospitalization). On an unknown date, the patient experienced ATRIAL FIBRILLATION (atrial fibrillation) and LYMPHOMA (lymphoma). On 15-Oct-2021, PERICARDITIS (inflamed pericardium) had resolved. At the time of the report, ATRIAL FIBRILLATION (atrial fibrillation) and LYMPHOMA (lymphoma) outcome was unknown. No concomitant medications were reported. No treatment medications were reported. This is a regulatory authority case concerning a 43-year-old, male patient with no relevant medical history, who experienced the expected serious events of Pericarditis and Non-serious events of Atrial fibrillation, Lymphoma. The events occurred approximately 3 months after the unknown dose of mRNA-1273 COVID 19 Vaccine. The rechallenge was not applicable, as information about further dosing was not disclosed. The event Pericarditis had resolved. The benefit-risk relationship of mRNA-1273 COVID 19 Vaccine, is not affected by this report. Most recent FOLLOW-UP information incorporated above includes: On 22-Dec-2021: Translation received on 23 Dec 2021, verbatim translated and indication translated.; Sender's Comments: This is a regulatory authority case concerning a 43-year-old, male patient with no relevant medical history, who experienced the expected serious events of Pericarditis and Non-serious events of Atrial fibrillation, Lymphoma. The events occurred approximately 3 months after the unknown dose of mRNA-1273 COVID 19 Vaccine. The rechallenge was not applicable, as information about further dosing was not disclosed. The event Pericarditis had resolved. The benefit-risk relationship of mRNA-1273 COVID 19 Vaccine, is not affected by this report.

Record is removed as of 4/29/2022

First Appeared on 1/14/2022

VAERS ID: 2023784

VAERS Form: 2

Age: 89.0

Sex: Male

Location: Foreign

Vaccinated: 2021-12-07

Onset: 2021-12-07

Submitted: 0000-00-00

Entered: 2022-01-11

Vaccination / Manufacturer (1 vaccine)	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	UNKNOWN / 3	- / -

Administered by: Other **Purchased by:** ??

Symptoms: Immunisation, Sudden cardiac death, SARS-CoV-2 test

Life Threatening? No

Birth Defect? No

Died? Yes

Date died: 2021-12-07

Permanent Disability? No

Recovered? No

Office Visit (V2.0)? No

ER or Office Visit (V1.0)? No

ER or ED Visit (V2.0)? No

Hospitalized? No

Previous Vaccinations:

Other Medications:

Current Illness:

Preexisting Conditions: Medical History/Concurrent Conditions: Asymptomatic COVID-19

Allergies:

Diagnostic Lab Data: Test Name: corona confirmed with test; Test Result: Positive

CDC 'Split Type': NLPFIZER INC202101869219

Write-up: booster; Sudden cardiac death; This is a spontaneous report received from a contactable reporter(s) (Consumer or other non HCP) from the Regulatory Authority-WEB. Regulatory number: NL-LRB-00732330. An 89-year-old male patient received bnt162b2 (COMIRNATY), administration date 07Dec2021 (Lot number: Unknown) at the age of 89 years as dose 3 (booster), single for COVID-19 immunisation. Relevant

medical history included: "Asymptomatic COVID-19" (unspecified if ongoing). The patient's concomitant medications were not reported. Vaccination history included: Comirnaty (DOSE 1, SINGLE), for COVID-19 immunisation, reaction(s): "No adverse effect"; Comirnaty (DOSE 2, SINGLE), for COVID-19 immunisation, reaction(s): "No adverse effect". The following information was reported: IMMUNISATION (death) with onset 07Dec2021, outcome "fatal", described as "booster"; SUDDEN CARDIAC DEATH (death) with onset 07Dec2021, outcome "fatal", described as "Sudden cardiac death". The patient underwent the following laboratory tests and procedures: sars-cov-2 test: positive. The reporter's father received his booster shot in the nursing home in the morning of 07Dec2021 and died in the afternoon of that same day (07Dec2021). The patient had no diagnostic procedures. The reported cause of death was cardiac failure. It was not reported if an autopsy was performed. Reporter Comment: BioNTech/Pfizer vaccine (Comirnaty) Passing away Additional information ADR: The reporter's father received his booster shot in the nursing home in the morning and died that same day in the afternoon. BSN available: yes COVID-19 Previous COVID-19 infection: disease symptoms: none Other diagnostic procedures: No. The lot number for bnt162b2 was not provided and will be requested during follow up.; Reporter's Comments: BioNTech/Pfizer vaccine (Comirnaty) Passing away Additional information ADR: The reporter's father received his booster shot in the nursing home in the morning and died that same day in the afternoon. BSN available: yes COVID-19 Previous COVID-19 infection: disease symptoms: none Other diagnostic procedures: No.; Reported Cause(s) of Death: Cardiac failure

Record is removed as of 6/3/2022

First Appeared on 2/11/2022

VAERS ID: 2097354

VAERS Form: 2

Age:

Sex: Female

Location: Foreign

Vaccinated: 2022-01-18

Onset: 2022-01-18

Submitted: 0000-00-00

Entered: 2022-02-09

Vaccination / Manufacturer (1 vaccine)	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	FF2382 / 3	- / -

Administered by: Other **Purchased by:** ??

Symptoms: Chills, Fatigue, Headache, Hyperpyrexia, Malaise, Myalgia, Nausea, Off label use, Vaccination site inflammation, Vaccination site pain, Vaccination site swelling, Interchange of vaccine products

Life Threatening? No

Birth Defect? No

Died? No

Permanent Disability? No

Recovered? No

Office Visit (V2.0)? No

ER or Office Visit (V1.0)? No

ER or ED Visit (V2.0)? No

Hospitalized? No

Previous Vaccinations:

Other Medications:

Current Illness:

Preexisting Conditions:

Allergies:

Diagnostic Lab Data: Test Date: 20220119; Test Name: hyperpyrexia; Result

Unstructured Data: Test Result:40.5 to 42 Centigrade

CDC 'Split Type': NLPFIZER INC202200137102

Write-up: Hyperpyrexia; Nausea; Malaise; Fatigue; Injection site pain; Injection site inflammation; Headache; Chills; Injection site swelling; Myalgia; past drug: Moderna vaccine; past drug: Moderna vaccine; This is a spontaneous report received from a contactable reporter (Consumer or other non HCP) from the Agency WEB. Regulatory

number: NL-LRB-00779431 (RA). A 43-year-old female patient received bnt162b2 (COMIRNATY), administration date 18Jan2022 (Lot number: FF2382) as dose 3 (booster), 0.3 ml single for covid-19 immunisation. The patient's relevant medical history and concomitant medications were not reported. Patient had no extensive swelling of vaccinated limb. Patient had no previous COVID-19 infection. Vaccination history included: Moderna vaccine (spikevax) (DOSE 1, 0.5mL), administration date: 12Mar2021, for COVID-19 immunization, reaction: "Pain at injection site"; Moderna vaccine (spikevax) (DOSE 2, 0.5mL), administration date: 09Apr2021, for COVID-19 immunization, reactions: "fever", "chills", "chest pressure", "palpitations", "headache", "nausea". The following information was reported: OFF LABEL USE (medically significant), INTERCHANGE OF VACCINE PRODUCTS (medically significant) all with onset 18Jan2022, outcome "unknown" and all described as "past drug: Moderna vaccine"; HYPERPYREXIA (medically significant) with onset 19Jan2022, outcome "recovering", described as "Hyperpyrexia"; NAUSEA (non-serious) with onset 19Jan2022, outcome "not recovered", described as "Nausea"; MALAISE (non-serious) with onset 19Jan2022, outcome "not recovered", described as "Malaise"; FATIGUE (non-serious) with onset 19Jan2022, outcome "not recovered", described as "Fatigue"; VACCINATION SITE PAIN (non-serious) with onset 19Jan2022, outcome "recovering", described as "Injection site pain"; VACCINATION SITE INFLAMMATION (non-serious) with onset 19Jan2022, outcome "recovering", described as "Injection site inflammation"; HEADACHE (non-serious) with onset 19Jan2022, outcome "not recovered", described as "Headache"; CHILLS (non-serious) with onset 19Jan2022, outcome "recovering", described as "Chills"; VACCINATION SITE SWELLING (non-serious) with onset 19Jan2022, outcome "recovering", described as "Injection site swelling"; MYALGIA (non-serious) with onset 19Jan2022, outcome "recovering", described as "Myalgia". The patient underwent the following laboratory tests and procedures: body temperature: (19Jan2022) 40.5 to 42. No follow-up attempts are possible. No further information is expected.

Record is removed as of 8/19/2022

First Appeared on 2/18/2022

VAERS ID: 2112236

VAERS Form: 2

Age:

Sex: Female

Location: Foreign

Vaccinated: 2021-06-30

Onset: 0000-00-00

Submitted: 0000-00-00

Entered: 2022-02-15

Vaccination / Manufacturer (1 vaccine)	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	- / 1	- / -

Administered by: Other **Purchased by:** ??

Symptoms: Drug ineffective, COVID-19, SARS-CoV-2 test positive

Life Threatening? No

Birth Defect? No

Died? No

Permanent Disability? No

Recovered? No

Office Visit (V2.0)? No

ER or Office Visit (V1.0)? No

ER or ED Visit (V2.0)? No

Hospitalized? No

Previous Vaccinations:

Other Medications:

Current Illness:

Preexisting Conditions: Medical History/Concurrent Conditions: COVID-19 (at 23:00:00)

Allergies:

Diagnostic Lab Data: Test Date: 20201230; Test Name: SARS-CoV-2 test positive; Result Unstructured Data: Test Result:SARS-CoV-2 test Positive

CDC 'Split Type': NLPFIZER INC202200252427

Write-up: Vaccination Failure; COVID-19; This is a spontaneous report received from a contactable reporter(s) (Consumer or other non HCP) from the Agency WEB. Other Case identifier(s): NL-LRB-00774930 (RA). A 18 year-old female patient received bnt162b2 (COMIRNATY), administration date 30Jun2021 (Lot number: Unknown) as dose 1, single and administration date 18Sep2021 (Lot number: Unknown) as dose 2,

single for covid-19 immunisation. Relevant medical history included: "COVID-19", start date: 30Dec2020 (unspecified if ongoing), notes: at 23:00:00. The patient's concomitant medications were not reported. The following information was reported: VACCINATION FAILURE (medically significant) with onset 30Dec2020, outcome "unknown", described as "Vaccination Failure"; COVID-19 (medically significant) with onset 30Dec2020, outcome "unknown", described as "COVID-19". The patient underwent the following laboratory tests and procedures: sars-cov-2 test positive: (30Dec2020) sars-cov-2 test positive, notes: at 23:00:00. No follow-up attempts are possible; information about lot/batch number cannot be obtained. No further information is expected.

Record is removed as of 6/24/2022

First Appeared on 2/25/2022

VAERS ID: 2139019

VAERS Form: 2

Age:

Sex: Female

Location: Foreign

Vaccinated: 2021-12-09

Onset: 2021-12-10

Submitted: 0000-00-00

Entered: 2022-02-25

Vaccination / Manufacturer (1 vaccine)	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	FF2382 / 3	- / -

Administered by: Other **Purchased by:** ??

Symptoms: Sudden death, SARS-CoV-2 test positive

Life Threatening? No

Birth Defect? No

Died? Yes

Date died: 2021-12-10

Permanent Disability? No

Recovered? No

Office Visit (V2.0)? No

ER or Office Visit (V1.0)? No

ER or ED Visit (V2.0)? No

Hospitalized? No

Previous Vaccinations:

Other Medications:

Current Illness:

Preexisting Conditions: Medical History/Concurrent Conditions: COVID-19 (disease symptoms: quite)

Allergies:

Diagnostic Lab Data: Test Date: 20210201; Test Name: corona, confirmed with test; Test Result: Positive

CDC 'Split Type': NLPFIZER INC202200253888

Write-up: Sudden death; This is a spontaneous report received from a contactable reporter(s) (Physician) from the regulatory authority-WEB. Regulatory number: NL-LRB-00789452. A 84 year-old female patient received bnt162b2 (COMIRNATY, strength: 0.3 mL), administration date 09Dec2021 (Lot number: FF2382) as dose 3 (booster), single

for covid-19 immunisation. Relevant medical history included: "COVID-19", start date: 01Feb2021 (unspecified if ongoing) disease symptoms: quite. The patient's concomitant medications were not reported. Vaccination history included: Comirnaty (Dose 1), administration date: 07Apr2021, for Covid-19 immunisation, reaction(s): "Fatigue", "Chills", "Myalgia", "Malaise"; Comirnaty (Dose 2), administration date: 12May2021, for Covid-19 immunisation, reaction(s): "Chills", "Fatigue", "Malaise", "Myalgia". The following information was reported: SUDDEN DEATH (death) with onset 10Dec2021, outcome "fatal", described as "Sudden death". The patient underwent the following laboratory tests and procedures: corona, confirmed with test: (01Feb2021) positive. The patient date of death was 10Dec2021. The reported cause of death was sudden death. It was not reported if an autopsy was performed. Additional information: patient was found dead in the night. No follow-up attempts are possible. No further information is expected.; Sender's Comments: Linked Report(s) : NL-PFIZER INC-202200262595 The same patient, different events after different doses; Reported Cause(s) of Death: Sudden death

Record is removed as of 9/2/2022