Manufacturer Report #: 202201224012

Pfizer Inc.
US Drug Safety Unit, MS712
100 Route 206 North
Peapack, NJ 07977

14-OCT-2022

Mr./Ms. Paul V Sheridan
DDM Consulting
22357 Columbia Street
Dearborn, MI 48124
UNITED STATES

Patient ID:	UNKNOWN
Suspect Product:	BNT162B2 (BNT162B2)
Reported Event Term(s):	heart failure
	blood clots
	mom double-jebbed in 3rd trimester

Dear Mr./Ms. Sheridan:

Thank you for taking the time to contact Pfizer Inc., regarding experience(s) that occurred while taking BNT162B2.

We would like to ask you to provide some further information on the experience you have reported and have attached a questionnaire we hope you will complete in this regard.

Pfizer Inc. is interested in learning as much as possible about adverse event(s) or potential adverse event (s) that have been reported with the use of our products and any further information you are able to provide would enable us to better evaluate this report. All such information provided to us is regarded as strictly confidential by Pfizer and by Health Authorities worldwide.

A postage-paid return envelope is enclosed for your convenience. Thank you once again for your cooperation.

Sincerely,
Safety Evaluation & Reporting
US Drug Safety Unit

If you are not the patient who was treated with above mentioned product(s) please provide

Patient's Name: _____ **Address:** _____

If available, please provide:

Drug Lot Number and Expiration Date: _____

Country of Occurrence: _____

Please provide the attached Questionnaire to your HCP for appropriate completion. If you're unable to provide it to the HCP, please complete the Questionnaire to the best of your knowledge.

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Pfizer/BioNTech COVID-19 Vaccine Follow-up Questionnaire

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PATIENT DETAILS

Patient Initials: _____ **Patient Age at Time of Vaccination:** _____ (Years)

PFIZER/BIONTECH COVID-19 VACCINE DETAILS

Dose	Date / Time	Site and Route of injection	Batch/Lot number
1st	Date (dd-Mmm-yyyy): Time (24hr):	Anatomical Site of injection: Route of administration: ☐Intramuscular *If other, please specify*	☐Not Available / Provided at Time of Report Completion ☐Obscured by Other Product Labelling ☐Misplaced/Discarded ☐Unable to Locate or Read the Details ☐Other, please specify
2nd	Date (dd-Mmm-yyyy): Time (24hr):	Anatomical Site of injection: Route of administration: ☐Intramuscular *If other, please specify*	☐Not Available / Provided at Time of Report Completion ☐Obscured by Other Product Labelling ☐Misplaced/Discarded ☐Unable to Locate or Read the Details ☐Other, please specify
3rd	Date (dd-Mmm-yyyy): Time (24hr):	Anatomical Site of injection: Route of administration: ☐Intramuscular *If other, please specify*	☐Not Available / Provided at Time of Report Completion ☐Obscured by Other Product Labelling ☐Misplaced/Discarded ☐Unable to Locate or Read the Details ☐Other, please specify
4th	Date (dd-Mmm-yyyy): Time (24hr):	Anatomical Site of injection: Route of administration: ☐Intramuscular *If other, please specify*	☐Not Available / Provided at Time of Report Completion ☐Obscured by Other Product Labelling ☐Misplaced/Discarded ☐Unable to Locate or Read the Details ☐Other, please specify

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COMPLETE IF A 3RD OR SUBSEQUENT DOSE WAS ADMINISTERED. CHECK ONE OPTION.

☐ Booster dose due to high risk of frequent institutional or occupational exposure to coronavirus (and at risk of serious COVID-19 complications)

☐ Booster dose due to a weakened immune system

If the reason is a weakened immune system, please select one of the conditions below:

- ☐ Current or recent cancer (including blood cancers such as Hodgkin's disease, leukemias, and myelomas)
- ☐ Advanced or untreated HIV infection
- ☐ Use of medications that suppress the immune system (e.g., high-dose of corticosteroids, cyclosporine, methotrexate, azathioprine, and biologic therapies like rituximab and etanercept)
- ☐ No/non-functioning, spleen or kidney failure
- ☐ Other, please specify: _____

☐ Booster dose (other)

Complete the below Vaccination Facility & Address for the most recent Covid 19 vaccine received (circle dose)

US ONLY

VACCINATION FACILITY TYPE

☐Doctor's Office/Urgent Care ☐Military Base
☐Hospital ☐Nursing Home/Senior Living Facility
☐Pharmacy or Drug Store ☐Public Health Clinic/Veterans Administration Facility
☐Workplace Clinic ☐Unknown
☐School/Student Health Clinic 1st dose 2nd dose 3rd dose/Booster 4th dose/Booster
☐Other, please specify: _____

Vaccine Administered at Military Facility? ☐Yes ☐No

VACCINATION FACILITY ADDRESS

Facility Name _____ **Zip Code** _____
Address _____ **State** _____
City _____ **Phone** _____
Country

PRIOR VACCINATIONS (within 4 weeks)
If applicable, list any other vaccinations within four weeks prior to the first administration date of the suspect vaccine(s)

☐None ☐Unknown

Vaccine Name	Manufacturer	Batch/Lot#	Route	Anatomical Site of Injection	No. of Previous Doses	Date (dd-Mmm-yyyy)

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Complete below for additional Vaccination Facility and Address (circle dose)

US ONLY

VACCINATION FACILITY TYPE

☐Doctor's Office/Urgent Care ☐Military Base
☐Hospital ☐Nursing Home/Senior Living Facility
☐Pharmacy or Drug Store ☐Public Health Clinic/Veterans Administration Facility
☐Workplace Clinic ☐Unknown
☐School/Student Health Clinic 1st dose 2nd dose 3rd dose/Booster 4th dose/Booster
☐Other, please specify: _____

Vaccine Administered at Military Facility? ☐Yes ☐No

VACCINATION FACILITY ADDRESS

Facility Name _____ **Zip Code** _____
Address _____ **State** _____
City _____ **Phone** _____
Country

Complete below for additional Vaccination Facility and Address (circle dose)

US ONLY

VACCINATION FACILITY TYPE

☐Doctor's Office/Urgent Care ☐Military Base
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☐Pharmacy or Drug Store ☐Public Health Clinic/Veterans Administration Facility
☐Workplace Clinic ☐Unknown
☐School/Student Health Clinic 1st dose 2nd dose 3rd dose/Booster 4th dose/Booster
☐Other, please specify: _____

Vaccine Administered at Military Facility? ☐Yes ☐No

VACCINATION FACILITY ADDRESS

Facility Name _____ **Zip Code** _____
Address _____ **State** _____
City _____ **Phone** _____
Country

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☐Other, please specify: _____

Vaccine Administered at Military Facility? ☐Yes ☐No

VACCINATION FACILITY ADDRESS

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CONCOMITANT DRUGS

List below concomitant drugs taken within two weeks before the event onset. Exclude all drugs only administered more than two weeks before the event, and any drug used to treat the event or taken after event onset.

☐None ☐Unknown

Drug Name (Trade and Generic)	Reason for Use	Route	Start Date	Stop Date	Check box if ongoing
					☐
					☐
					☐
					☐

PATIENT'S MEDICAL HISTORY (including any illness at time of vaccination)

☐None ☐Unknown

Illness/AE	Onset Date (dd-Mmm-yyyy)	Stop Date (check box if ongoing)	Pertinent Details (Include surgical procedures and dates)
		☐*Ongoing*	
		☐*Ongoing*	
		☐*Ongoing*	
		☐*Ongoing*	

FAMILY MEDICAL HISTORY RELEVANT TO AE(S)

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RELEVANT TESTS

List other relevant diagnostic and confirmatory test results for event(s), for example, from blood tests, cerebro-spinal fluid culture, pleural fluid culture, urine culture, diagnostic imaging (e.g., chest X-ray, MRI). If COVID-19 testing has been conducted, provide test dates and results.

☐None ☐Unknown

Test	Date (dd-Mmm-yyyy)	Result	Units	Norm Low	Norm High	Comments

SPECIFIC RELEVANT TEST FOR THROMBOEMBOLIC EVENTS WITH THROMBOCYTOPENIA

☐None ☐Unknown

Test	Date (dd-Mmm-yyyy)	Result	Units	Norm Low	Norm High	Comments
Antibody test to platelet factor IV						

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ADVERSE EVENTS NOTE: FOR THROMBOEMBOLIC EVENTS WITH THROMBOCYTOPENIA INCLUDE SPECIFIC RELEVANT TEST ABOVE				
Term/Date/Time	**Seriousness Criteria**	**AE required visit to**	**AE Outcome**	**Treatment**
AE Term: Onset Date: (dd-Mmm-yyyy) Onset Time*: (24hr) ** Time only needed when event is on day of vaccination*	☐Not serious *If serious, check all that apply* ☐Resulted in death ☐Life-threatening ☐Hospitalization/ Prolongation of hosp. ☐Persistent/Significant disability/Incapacity ☐Important medical event *If hospitalized* Duration of stay:	*Check all that apply* ☐Emergency Room ☐Physician Office ☐Intensive Care Unit *If admitted to ICU* Duration of stay:	☐Recovered ☐Recovered with sequelae ☐Recovering ☐Not Recovered ☐Fatal ☐Unknown *If recovered or recovered with sequelae* Date of Recovery: *If fatal* Date of Death:	*Did the event require the initiation of new medication/other treatment/ procedure?* ☐Yes ☐No ☐Unknown *If yes* Details:
AE Term: Onset Date: (dd-Mmm-yyyy) Onset Time*: (24hr) ** Time only needed when event is on day of vaccination*	☐Not serious *If serious, check all that apply* ☐Resulted in death ☐Life-threatening ☐Hospitalization/ Prolongation of hosp. ☐Persistent/Significant disability/Incapacity ☐Important medical event *If hospitalized* Duration of stay:	*Check all that apply* ☐Emergency Room ☐Physician Office ☐Intensive Care Unit *If admitted to ICU* Duration of stay:	☐Recovered ☐Recovered with sequelae ☐Recovering ☐Not Recovered ☐Fatal ☐Unknown *If recovered or recovered with sequelae* Date of Recovery: *If fatal* Date of Death:	*Did the event require the initiation of new medication/other treatment/ procedure?* ☐Yes ☐No ☐Unknown *If yes* Details:

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AE Term: Onset Date: (dd-Mmm-yyyy) Onset Time*: (24hr) ** Time only needed when event is on day of vaccination*	☐Not serious *If serious, check all that apply* ☐Resulted in death ☐Life-threatening ☐Hospitalization/ Prolongation of hosp. ☐Persistent/Significant disability/Incapacity ☐Important medical event *If hospitalized* Duration of stay:	*Check all that apply* ☐Emergency Room ☐Physician Office ☐Intensive Care Unit *If admitted to ICU* Duration of stay:	☐Recovered ☐Recovered with sequelae ☐Recovering ☐Not Recovered ☐Fatal ☐Unknown *If recovered or recovered with sequelae* Date of Recovery: *If fatal* Date of Death:	*Did the event require the initiation of new medication/other treatment/ procedure?* ☐Yes ☐No ☐Unknown *If yes* Details:

AUTOPSY INFORMATION
In case of death, was an autopsy done? ☐ Yes ☐ No ☐ Unknown If Yes, provide autopsy results:

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COMMENTS/NARRATIVE

Provide clear narrative description of the sequence of event(s), diagnosis, treatment, and any other relevant details.

Please answer the following questions:

1. Please clarify the type of medication error.
2. Please provide the stage of medication error (e.g., prescribing, dispensing, preparation, and administration).
3. Please provide contributing factors to the medication error.
4. Please clarify if the medication error affected the patient or consumer with clinical consequences.

REPORTER INFORMATION

Name of individual filling out this form: _____

Facility Address: _____

City, State, Zip Code: _____

Country: _____

☐Physician
☐Pharmacist
☐Nurse
☐Other, please specify

Telephone Number: _____ **Email Address:** _____

May we contact you to request additional information if needed? ☐Yes ☐No

Date: **Signature:**