

SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last) PRIVACY	1a. COUNTRY UNITED STATES	2. DATE OF BIRTH Day Month Year (b) (6) 1974	2a. AGE 46 Years	3. SEX Male	3a. WEIGHT 74.00 kg	4-6 REACTION ONSET Day Month Year 31 AUG 2020	8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION <input type="checkbox"/> PATIENT DIED <input checked="" type="checkbox"/> INVOLVED OR PROLONGED INPATIENT HOSPITALISATION <input type="checkbox"/> INVOLVED PERSISTENT OR SIGNIFICANT DISABILITY OR INCAPACITY <input type="checkbox"/> LIFE THREATENING
7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data) Event Verbatim [PREFERRED TERM] (Related symptoms if any separated by commas) Deep vein thrombosis [Deep vein thrombosis] Case Description: A PHASE 1/2/3, PLACEBO-CONTROLLED, RANDOMIZED, OBSERVER-BLIND, DOSE-FINDING STUDY TO EVALUATE THE SAFETY, TOLERABILITY, IMMUNOGENICITY, AND EFFICACY OF SARS-COV-2 RNA VACCINE CANDIDATES AGAINST COVID-19 IN HEALTHY ADULTS This is a report from a Pfizer-Sponsored Interventional Study source for Protocol C4591001 sponsored by BioNTech, managed and reported by (Continued on Additional Information Page)							

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name) #1) BNT162;PLACEBO (Code not broken)	20. DID REACTION ABATE AFTER STOPPING DRUG? <input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> NA
15. DAILY DOSE(S) Blinded, Information withheld.	16. ROUTE(S) OF ADMINISTRATION Blinded, Information withheld.
17. INDICATION(S) FOR USE #1) Immunization (Immunisation)	21. DID REACTION REAPPEAR AFTER REINTRODUCTION? <input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> NA
18. THERAPY DATES(from/to) #1) 20-AUG-2020 11:44:00 / 20-AUG-2020 11:44:00	19. THERAPY DURATION #1) Unknown

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction) #1) INSULIN (INSULIN) ; 10-DEC-2016 / Ongoing #2) INSULIN GLARGINE (INSULIN GLARGINE) ; 10-DEC-2016 / Ongoing		
23. OTHER RELEVANT HISTORY. (e.g. diagnostics, allergies, pregnancy with last month of period, etc.) From/To Dates AUG-2014 to Ongoing 20-AUG-2020 to 02-SEP-2020	Type of History / Notes Relevant Med History Relevant Med History	Description Type 1 diabetes mellitus (Type 1 diabetes mellitus) COVID-19 (COVID-19)

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER Pfizer Inc Head Drug Safety Surveillance 219 East 42nd Street New York, New York 10017 UNITED STATES Phone: 212 733 5544	26. REMARKS
24b. MFR CONTROL NO. 2020347643	25b. NAME AND ADDRESS OF REPORTER Hector A. Rodriguez
24c. DATE RECEIVED BY MANUFACTURER 16-SEP-2020	25a. REPORT TYPE <input checked="" type="checkbox"/> STUDY <input type="checkbox"/> LITERATURE <input checked="" type="checkbox"/> HEALTH PROFESSIONAL <input type="checkbox"/> OTHER: UNITED STATES Lizz L Hernandez Diaz 2400 NW 54th Street Miami, FL 33142 UNITED STATES
DATE OF THIS REPORT 02-MAY-2021	25a. REPORT TYPE <input type="checkbox"/> INITIAL <input type="checkbox"/> FOLLOWUP:

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Pfizer on the sponsors behalf.

A 46-year-old male subject received BNT162:PLACEBO, intramuscular in the left deltoid, on 20Aug2020 at 11:44 (b) (6) as a single dose for immunization. Medical history included type 1 diabetes mellitus from Aug2014 and ongoing, and Covid-19 from 20Aug2020 to 02Sep2020. Family medical history relevant to adverse event (AEs) was provided as none. Ongoing concomitant medication included insulin (regular), and insulin glargine, both for type 1 diabetes mellitus from 10Dec2016. The subject experienced deep vein thrombosis on 31Aug2020, which required a visit to the emergency room and was considered serious due to hospitalization for 3 days. Per the investigator, on 01Sep2020, per verbal account, patient presented to ER for cough and calf pain on 31Aug2020. After performing spiral CT thrombus was visualized. Taking into account the subject's advanced age and history of T1DM, which made him prone to developing clots, may have placed him at higher risk for developing deep vein thromboses. The event required a visit to the emergency room and not the physician office. The subject was admitted on 31Aug2020 (reported hospital stay was 3 days), with bilateral calf pain and hyperglycemia due to noncompliance. The subject was given insulin regular (NOVOLIN R) 15 units subcutaneously (SQ). CT angio diagnosed Covid pneumonia. The subject had already been diagnosed with Covid, but during this hospital visit was mostly asymptomatic and did not require supplemental oxygen. A CT angio was done in the emergency department (ED), which diagnosed the pulmonary emboli (PE) after lower extremity dopplers were negative. The subject was started on enoxaparin sodium (LOVENOX) bridged to apixaban. His sugars had been well controlled since resuming insulin. Covid pneumonia was considered resolved. The subject was discharged on 02Sep2020 with the following medications for pulmonary embolism secondary to deep vein thrombosis (DVT): apixaban 10mg orally 2x/day for 7 days followed by 5mg orally 2x/day, acetaminophen (TYLENOL) 650mg every 4 hours as needed (PRN), ibuprofen 600mg every 8 hours PRN for 14 days. The subject was seen at the research site to acquire nasal swab and still appeared to be in noticeable pain. A follow-up was placed on 16Sep2020 where the subject stated that all symptoms has resolved as of 09Sep2020, and would remain on apixaban for at least 6 months. There were no concomitant vaccines, prior vaccines within 4 weeks, or any AEs following prior vaccinations within 4 weeks. The subject underwent lab tests and procedures which included spiral computerised tomogram (CT) which showed thrombus was visualized on an unspecified date in 2020. On 01Sep2020, D-Dimer was 1.66 mg/L (normal range: 0.0 to 0.5). On 31Aug2020, SARS-COV-2 with unknown results (comments: Xpert@Xpress SARS-CoV-2), C-reactive protein (HS-CRP) was 8.1 mg/L (normal range: 0.1 to 3.0), and CT Angiography with result of 1. several bilateral segmental to subsegmental pulmonary emboli. 2. Patchy peripheral opacities were seen bilaterally likely reflecting an infectious process. Given the history, was most likely covid infection; the presence of more consolidative opacity rather than ground glass was atypical, but could indicate some evolution of airspace opacities associated with COVID. A concomitant/superimposed infectious process was possible. The action taken in response to the event for BNT162:PLACEBO was not applicable (reported as dose not changed). The outcome of the event was recovered on 09Sep2020.

The investigator considered there was not a reasonable possibility that the serious adverse event was related to blinded vaccine therapy, concomitant medications, or clinical trial procedure. It is in the investigator's medical opinion that the investigational vaccine did not cause the event nor did it exacerbate anything pre-existing.

Follow-up (16Sep2020): New information received includes: reaction data (updated event outcome and recovery date), laboratory details, relevant medical history, and clinical course details (including hospitalization and other medications given).

Case Comment: The company reasonably does not attribute the case to blinded study vaccine, concomitant drugs or clinical trial procedure based on the information currently available, the known adverse event profile of the suspect product and the pathophysiology of the event.

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1		Angiogram	Covid pneumonia	
2	31-AUG-2020	Angiogram	1. several bilateral segmental to subsegmental pulmonary emboli. 2. Patchy peripheral opacities were seen bilaterally likely reflecting an infectious process. Given the history, was most likely covid infection; the presence of more consolidative opacity rather than ground glass was atypical, but could indicate some evolution of airspace opacities associated with COVID. A concomitant/superimposed infectious process was possible	
3	31-AUG-2020	C-reactive protein	8.1 mg/l	3.0 0.1
4	2020	Computerised tomogram	thrombus	
		thrombus was visualized		

ADDITIONAL INFORMATION**13. Lab Data**

#	Date	Test / Assessment / Notes	Results	Normal High / Low
5	01-SEP-2020	Fibrin D dimer	1.66 mg/l	0.5 0.0
6	31-AUG-2020	SARS-CoV-2 test Xpert@Xpress SARS-CoV-2	unknown result	
7		Smear test	unknown results	
8		Ultrasound Doppler Negative	negative	

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SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last) PRIVACY	1a. COUNTRY UNITED STATES	2. DATE OF BIRTH Day Month Year (b) (6) 1989	2a. AGE 31 Years	3. SEX Male	3a. WEIGHT 80.27 kg	4-6 REACTION ONSET Day Month Year 27 NOV 2020	8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data) Event Verbatim [PREFERRED TERM] (Related symptoms if any separated by commas) Other Serious Criteria: Medically Significant Acute bilateral segmental and subsegmental pulmonary embolism [Pulmonary embolism] DVT, Left leg [Deep vein thrombosis] Case Description: A PHASE 1/2/3, PLACEBO-CONTROLLED, RANDOMIZED, OBSERVER-BLIND, DOSE-FINDING STUDY TO EVALUATE THE SAFETY, TOLERABILITY, IMMUNOGENICITY, AND EFFICACY OF SARS-COV-2 RNA VACCINE CANDIDATES AGAINST COVID-19 IN HEALTHY INDIVIDUALS							<input type="checkbox"/> PATIENT DIED <input checked="" type="checkbox"/> INVOLVED OR PROLONGED INPATIENT HOSPITALISATION <input type="checkbox"/> INVOLVED PERSISTENT OR SIGNIFICANT DISABILITY OR INCAPACITY <input checked="" type="checkbox"/> LIFE THREATENING

(Continued on Additional Information Page)

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name) #1) BNT162;PLACEBO (Code not broken)	20. DID REACTION ABATE AFTER STOPPING DRUG? <input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> NA
15. DAILY DOSE(S) Blinded, Information withheld.	16. ROUTE(S) OF ADMINISTRATION Blinded, Information withheld.
17. INDICATION(S) FOR USE #1) Covid-19 immunization (COVID-19 immunisation)	21. DID REACTION REAPPEAR AFTER REINTRODUCTION? <input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> NA
18. THERAPY DATES(from/to) #1) 27-AUG-2020 09:20:00 / 27-AUG-2020 09:20:00	19. THERAPY DURATION #1) Unknown

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction) #1) FINASTERIDE (FINASTERIDE) ; MAR-2020 / Ongoing #2) NAPROXEN (NAPROXEN) ; 27-NOV-2020 / Ongoing	
23. OTHER RELEVANT HISTORY. (e.g. diagnostics, allergies, pregnancy with last month of period, etc.) From/To Dates 06-AUG-2020 to 06-AUG-2020 2014 to Ongoing	Type of History / Notes Historical Vaccine dose 1 intramuscularly at left deltoid at 12:29 Relevant Med History Alopecia (Alopecia)

(Continued on Additional Information Page)

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER Pfizer Inc Head Drug Safety Surveillance 219 East 42nd Street New York, New York 10017 UNITED STATES Phone: 212 733 5544	26. REMARKS
24b. MFR CONTROL NO. 2020503990	25b. NAME AND ADDRESS OF REPORTER Veronic Fragoso
24c. DATE RECEIVED BY MANUFACTURER 12-MAR-2021	24d. REPORT SOURCE <input checked="" type="checkbox"/> STUDY <input type="checkbox"/> LITERATURE <input checked="" type="checkbox"/> HEALTH PROFESSIONAL <input type="checkbox"/> OTHER:
DATE OF THIS REPORT 02-MAY-2021	25a. REPORT TYPE <input type="checkbox"/> INITIAL <input type="checkbox"/> FOLLOWUP:

UNITED STATES
(b) (6)

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

This is a report from an interventional study source for Protocol C4591001 sponsored by BioNTech, managed and reported by Pfizer on the sponsor's behalf.

A 31-year-old male subject received the first dose of blinded study vaccine (BNT162; PLACEBO) on 06Aug2020 at 12:29 and second dose on 27Aug2020 at 09:20, both intramuscularly (IM) at left deltoid at single doses for Covid-19 immunization. Medical history included alopecia from 2014 and ongoing. Subject also reported history of coagulation disorders in the family, included his (b) (6) and possibly (b) (6). The subject was positive for human leukocyte antigen (HLA)-B27, which had been found to increase risk for DVT. Additionally, Subject's (b) (6) was heterozygous for prothrombin g20210a mutation. Concomitant medications included finasteride for alopecia from Mar2020 and ongoing and naproxen for left leg pain from 27Nov2020 and ongoing. Concomitant vaccines administered on the same date of investigational vaccine and prior vaccinations within 4 weeks were none. The subject experienced DVT, left leg on 27Nov2020 considered serious medically significant and resulted in hospitalization. On 14Dec2020, the subject experienced acute bilateral segmental and subsegmental pulmonary embolism which was considered life threatening event and resulted in hospitalization. Both the events required a visit to the emergency room and physician office. The clinical course was as follows: Subject stated he had strained his left calf on 27Nov2020 and had swelling that had not resolved. Magnetic resonance imaging (MRI) and doppler ultrasound on 11Dec2020 were positive deep vein thrombosis (DVT) in the left leg and subject was sent to the emergency room (ER) for further evaluation. While admitted they ordered a spiral computed tomography (CT) Scan which confirmed diagnosis of bilateral pulmonary embolisms. Pertinent imaging confirmed diagnosis of DVT of left leg and pulmonary embolism (PE). Computed tomography angiography (CTA) completed on 14Dec2020 bilateral segmental and subsegmental pulmonary emboli involving the right upper lobe, right middle lobe, right lower lobe and left lower lobe. Venous duplex doppler 14Dec2020 confirmed extensive DVT of the left lower extremity (LLE). Subject admitted to medicine team for evaluation of DVT of LLE and bilateral segmental and subsegmental PE. Subject remained asymptomatic without symptoms of chest pain or shortness of breath (SOB). The subject was hemodynamically stable with oxygen (O2) saturations of 96% on room air (RA). Transthoracic echocardiogram (TTE) performed showed mild right ventricle (RV) strain and mild dilation. Vascular surgery consulted and deemed no surgical interventions were necessary. On 14Dec2020, nasal swab Covid-19 qualitative polymerase chain reaction (PCR) test was negative. Possible provoking factor include a 3 hours car trip to a city during the thanksgiving weekend, and recent injury to the left leg with prolonged period of immobilization (3 weeks). The subject was treated with a heparin drip and per the vascular team was deemed stable and discharged home on Tuesday evening (15Dec2020). It was reported that the subject was currently was asymptomatic and feeling well. The subject was advised to establish care with primary care physician (PCP) in 1 week and outpatient hematologist in 2 weeks for hypercoagulability work-up. Subject was discharged on apixaban (ELIQUIS) 10mg twice a day (BID) for 7 days and then a maintenance dose of 10mg daily. The action taken in response to the event for blinded study vaccine was not applicable. The outcome of the events was recovering.

The investigator considered there was not a reasonable possibility that the events DVT, left leg and Acute bilateral segmental and subsegmental pulmonary embolism were related to blinded study vaccine (BNT162; PLACEBO), concomitant drugs or clinical trial procedure.

Follow-up (19Jan2021): New information received includes: updated the event onset date (from 27Nov2020 to 14Dec2020) and indication for study drug.

Follow-up (06Feb2021): New information received includes: updated the event onset date (from 14Dec2020 to 27Nov2020), relevant tests, family medical history, treatment details and clinical course.

Amendment: This follow-up report is being submitted to amend previously reported information: sequence in narrative.

Follow-up (26Feb2021): New information received includes: clinical course (unknown if Covid test was done).

Amendment: This follow-up report is being submitted to amend previously reported information: update onset date of " pulmonary embolism, bilateral lungs" from 27Nov2020 to 14Dec2020.

Follow-up (12Mar2021): New information received includes: reaction data (event VT 'pulmonary embolism, bilateral lungs' updated to 'acute bilateral segmental and subsegmental pulmonary embolism,' additional seriousness criterion life threatening event for event 'Acute bilateral segmental and subsegmental pulmonary embolism', additional seriousness criterion medically significant for event 'DVT, Left leg') and laboratory data (Covid-19 test as negative).

Case Comment: The company reasonably does not attribute the case to blinded study vaccine, (BNT162;PLACEBO) concomitant drugs or clinical trial procedure based on the information currently available, on the pathophysiology of the events and the temporal relationship (latency of 3 months).

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1	14-DEC-2020	Angiogram	bilateral segmental and subsegmental pulmonary	

ADDITIONAL INFORMATION**13. Lab Data**

#	Date	Test / Assessment / Notes	Results	Normal High / Low
		bilateral segmental and subsegmental pulmonary emboli involving the right upper lobe, right middle lobe, right lower lobe and left lower lobe		
2		Computerised tomogram	confirmed diagnosis of bilateral pulmonary embolisms.	
3		Echocardiogram	mild RV strain and mild dilation	
4		HLA marker study Positive	Positive	
5	11-DEC-2020	Magnetic resonance imaging Positive	DVT positive	
6		Oxygen saturation RA	96 %	
7	14-DEC-2020	SARS-CoV-2 test Negative	negative	
8	11-DEC-2020	Ultrasound Doppler Positive	DVT positive	
9	14-DEC-2020	Ultrasound Doppler	extensive DVT of the left lower extremity	

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
06-AUG-2020 to 06-AUG-2020	Historical Vaccine	BNT162;PLACEBO (BLINDED THERAPY); Drug Indication: COVID-19 immunization (COVID-19 immunisation) dose 1 intramuscularly at left deltoid at 12:29
Unknown	Relevant Med History his (b) (6) and possibly	Coagulation disorder (Coagulopathy); (b) (6)

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SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last) PRIVACY	1a. COUNTRY UNITED STATES	2. DATE OF BIRTH Day Month Year (b) (6) 1991	2a. AGE 29 Years	3. SEX Female	3a. WEIGHT 52.50 kg	4-6 REACTION ONSET Day Month Year 20 DEC 2020	8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION <input type="checkbox"/> PATIENT DIED <input checked="" type="checkbox"/> INVOLVED OR PROLONGED INPATIENT HOSPITALISATION <input type="checkbox"/> INVOLVED PERSISTENT OR SIGNIFICANT DISABILITY OR INCAPACITY <input type="checkbox"/> LIFE THREATENING
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7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data)
Event Verbatim [PREFERRED TERM] (Related symptoms if any separated by commas)
acute DVT left upper extremity [Deep vein thrombosis]

Case Description: A PHASE 1/2/3, PLACEBO-CONTROLLED, RANDOMIZED, OBSERVER-BLIND, DOSE-FINDING STUDY TO EVALUATE THE SAFETY, TOLERABILITY, IMMUNOGENICITY, AND EFFICACY OF SARS-COV-2 RNA VACCINE CANDIDATES AGAINST COVID-19 IN HEALTHY INDIVIDUALS

This is a report from an interventional study source for Protocol C4591001 sponsored by BioNTech, managed and reported by Pfizer on the sponsor's

(Continued on Additional Information Page)

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name) #1) BNT162;PLACEBO (Code not broken) #2) YAZ (DROSPIRENONE, ETHINYLESTRADIOL BETADEx (Continued on Additional Information Page)	20. DID REACTION ABATE AFTER STOPPING DRUG? <input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> NA
15. DAILY DOSE(S) Blinded, Information withheld. #2) [drospirenone (Continued on Additional Information Page)]	16. ROUTE(S) OF ADMINISTRATION Blinded, Information withheld. #2) Oral
17. INDICATION(S) FOR USE #1) COVID-19 immunisation (COVID-19 immunisation) #2) contraception (Contraception)	21. DID REACTION REAPPEAR AFTER REINTRODUCTION? <input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> NA
18. THERAPY DATES(from/to) #1) 27-AUG-2020 13:30:00 / 27-AUG-2020 13:30:00 #2) JUN-2010 / 21-DEC-2020	19. THERAPY DURATION #1) Unknown #2) Unknown

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction) #1) CLONAZEPAM (CLONAZEPAM) ; JAN-2006 / Ongoing #2) FLUOXETINE (FLUOXETINE) ; FEB-2020 / Ongoing #3) ZYRTEC [LEVOCABASTINE HYDROCHLORIDE] (LEVOCABASTINE) (Continued on Additional Information Page)
23. OTHER RELEVANT HISTORY. (e.g. diagnostics, allergies, pregnancy with last month of period, etc.) From/To Dates Type of History / Notes Description 06-AUG-2020 to 06-AUG-2020 Historical Vaccine Dose 1 at 11:25; IM, left deltoid JAN-2006 to Ongoing Relevant Med History Anxiety (Anxiety) (Continued on Additional Information Page)

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER Pfizer Inc Head Drug Safety Surveillance 219 East 42nd Street New York, New York 10017 UNITED STATES Phone: 212 733 5544	26. REMARKS
24b. MFR CONTROL NO. 2020506317	25b. NAME AND ADDRESS OF REPORTER Dr. Michael Dever MD
24c. DATE RECEIVED BY MANUFACTURER 10-FEB-2021	24d. REPORT SOURCE <input checked="" type="checkbox"/> STUDY <input type="checkbox"/> LITERATURE <input checked="" type="checkbox"/> HEALTH PROFESSIONAL <input type="checkbox"/> OTHER:
DATE OF THIS REPORT 02-MAY-2021	25a. REPORT TYPE <input type="checkbox"/> INITIAL <input type="checkbox"/> FOLLOWUP:
UNITED STATES Rebecca Klipper 618 E South St. Suite 100 Orlando, FL 32801 UNITED STATES (Continued on Additional Information Page)	

ADDITIONAL INFORMATION**7+13. DESCRIBE REACTION(S) continued**

behalf.

A 29-year-old female subject received first dose of blinded study vaccine (BNT162:PLACEBO) on 06Aug2020 at 11:25 and second dose on 27Aug2020 at 13:30, both via intramuscular (IM) at left deltoid as single doses for COVID-19 immunisation. The subject received suspect concomitant drug drospirenone/ethinylestradiol betadex clathrate (YAZ) for contraception via oral (PO) at 3/0.02 mg, once daily (QD) from Jun2010 to 21Dec2020. Most recent dose was on 20Dec2020. Medical history included seizures from 2004 to 2008, anxiety from Jan2006 and ongoing, depression and environmental allergies both from Feb2020 and ongoing, left (L) torn labrum and L labrum repair both in Sep2011. Other concomitant drugs included clonazepam for anxiety from Jan2006, fluoxetine for depression from Feb2020, and levocabastine hydrochloride (ZYRTEC) for environmental allergies from Feb2020, all were ongoing and most recent dose was on 20Dec2020. There were no concomitant vaccines, prior vaccinations (within 4 weeks) or family medical history relevant to adverse event (AE). On 20Dec2020, the subject experienced acute deep vein thrombosis (DVT) left upper extremity, which required a visit to emergency room and subsequent hospitalization for 1 day. The clinical course was as follows: Subject was experiencing swelling, discoloration and pain in left arm that caused her to go to the emergency room. It was discovered through an ultrasound that she had a blood clot. Other testing was being done currently to confirm there were no other blood clots elsewhere. No covid testing results received from hospital and no covid testing noted in hospital records received as well. Subject was discharged on rivaroxaban (XARELTO). Relevant test included venous doppler which showed positive for DVT on 20Dec2020. The subject had arm pain for a week prior to seeking medical care. The subject was still taking medication and as such still going. The last action taken in response to event for the blinded study vaccine was not applicable, while for suspect drug drospirenone/ethinylestradiol betadex clathrate was permanently withdrawn on 21Dec2020. The clinical outcome of the event was recovering.

The investigator considered there was a reasonable possibility that the event acute DVT left upper extremity was related to suspect concomitant drug drospirenone/ethinylestradiol betadex clathrate, physicians believed it was related to subject's long term use of contraceptive. But the investigator considered there was not a reasonable possibility that the event was related to blinded study vaccine, other concomitant drugs or clinical trial procedure.

Follow-up (15Jan2021): New information reported includes: relevant test and confirmation that no covid testing results received from hospital.

Follow-up (28Jan2021): New information reported includes: site confirmed that no covid testing noted in hospital records received.

Amendment: This follow-up report is being submitted to amend previously reported information: reporter details.

Follow-up (10Feb2021): New information reported includes: clinical course (event details).

Case Comment: The company reasonably does not attribute the case to blinded study vaccine, (BNT162:PLACEBO) concomitant drugs or clinical trial procedure based on the information currently available and on the pathophysiology of the event.

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1		Laboratory test	unknown results	
		to confirm there were no other blood clots elsewhere.		
2	20-DEC-2020	Ultrasound Doppler Positive	positive for DVT	
3		Ultrasound scan	blood clot	

14-19. SUSPECT DRUG(S) continued

14. SUSPECT DRUG(S) (include generic name)	15. DAILY DOSE(S); 16. ROUTE(S) OF ADMIN	17. INDICATION(S) FOR USE	18. THERAPY DATES (from/to); 19. THERAPY DURATION
#2) YAZ (DROSPIRENONE, ETHINYLESTRADIOL BETADEX CLATHRATE) ; Regimen #1	[drospirenone 3 mg]/[ethinylestradiol betadex clathrate 0.02 mg], 1x/day; Oral	contraception (Contraception)	JUN-2010 / 21-DEC-2020; Unknown

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION continued

#3) ZYRTEC [LEVOCABASTINE HYDROCHLORIDE] (LEVOCABASTINE HYDROCHLORIDE) Tablet ; FEB-2020 / Ongoing

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ADDITIONAL INFORMATION**23. OTHER RELEVANT HISTORY continued**

From/To Dates	Type of History / Notes	Description
06-AUG-2020 to 06-AUG-2020	Historical Vaccine	BNT162;PLACEBO (BLINDED THERAPY); Drug Indication: COVID-19 immunisation (COVID-19 immunisation) Dose 1 at 11:25; IM, left deltoid
FEB-2020 to Ongoing	Relevant Med History	Depression (Depression);
FEB-2020 to Ongoing	Relevant Med History	Environmental allergy (Hypersensitivity);
SEP-2011 to SEP-2011	Relevant Med History	Cartilage injury (Cartilage injury); left torn labrum
SEP-2011 to SEP-2011	Relevant Med History	Cartilage repair (Chondroplasty); L labrum repair
2004 to 2008	Relevant Med History	Seizures (Seizure);

25b. Name And Address of Reporters continued
Dr. Michael Dever MD

UNITED STATES

Rebecca Klipper
618 E South St. Suite 100
Orlando, FL 32801
UNITED STATES

(b) (6)

Beckie Klipper
618 E South St. Suite 100
Orlando, FL 32801
UNITED STATES

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SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last) PRIVACY	1a. COUNTRY UNITED STATES	2. DATE OF BIRTH Day Month Year (b) (6) 2003	2a. AGE 16 Years	3. SEX Female	3a. WEIGHT 102.70 kg	4-6 REACTION ONSET Day Month Year 15 NOV 2020	8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data) Event Verbatim [PREFERRED TERM] (Related symptoms if any separated by commas) right lower extremity DVT [Deep vein thrombosis] Case Description: A PHASE 1/2/3, PLACEBO-CONTROLLED, RANDOMIZED, OBSERVER-BLIND, DOSE-FINDING STUDY TO EVALUATE THE SAFETY, TOLERABILITY, IMMUNOGENICITY, AND EFFICACY OF SARS-COV-2 RNA VACCINE CANDIDATES AGAINST COVID-19 IN HEALTHY INDIVIDUALS This is a report from an interventional study source for Protocol C4591001 sponsored by BioNTech, managed and reported by Pfizer on the sponsor's							<input type="checkbox"/> PATIENT DIED <input checked="" type="checkbox"/> INVOLVED OR PROLONGED INPATIENT HOSPITALISATION <input type="checkbox"/> INVOLVED PERSISTENT OR SIGNIFICANT DISABILITY OR INCAPACITY <input type="checkbox"/> LIFE THREATENING

(Continued on Additional Information Page)

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name) #1) BNT162;PLACEBO (Code not broken)	20. DID REACTION ABATE AFTER STOPPING DRUG? <input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> NA
15. DAILY DOSE(S) Blinded, Information withheld.	16. ROUTE(S) OF ADMINISTRATION Blinded, Information withheld.
17. INDICATION(S) FOR USE #1) COVID-19 immunization (COVID-19 immunisation)	21. DID REACTION REAPPEAR AFTER REINTRODUCTION? <input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> NA
18. THERAPY DATES(from/to) #1) 27-OCT-2020 14:25:00 / 27-OCT-2020 14:25:00	19. THERAPY DURATION #1) Unknown

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)	
23. OTHER RELEVANT HISTORY. (e.g. diagnostics, allergies, pregnancy with last month of period, etc.) From/To Dates Type of History / Notes Description 07-OCT-2020 to 07-OCT-2020 Historical Vaccine 11-SEP-2020 to Ongoing Relevant Med History Ankle fracture (Ankle fracture) right	

(Continued on Additional Information Page)

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER Pfizer Inc Head Drug Safety Surveillance 219 East 42nd Street New York, New York 10017 UNITED STATES Phone: 212 733 5544	26. REMARKS
24b. MFR CONTROL NO. 2020511163	25b. NAME AND ADDRESS OF REPORTER Michael Dever MD
24c. DATE RECEIVED BY MANUFACTURER 08-FEB-2021	25a. REPORT TYPE <input type="checkbox"/> INITIAL <input type="checkbox"/> FOLLOWUP:
24d. REPORT SOURCE <input checked="" type="checkbox"/> STUDY <input type="checkbox"/> LITERATURE <input checked="" type="checkbox"/> HEALTH PROFESSIONAL <input type="checkbox"/> OTHER:	UNITED STATES Chanel Adams ARNP
DATE OF THIS REPORT 02-MAY-2021	UNITED STATES (Continued on Additional Information Page)

ADDITIONAL INFORMATION**7+13. DESCRIBE REACTION(S) continued**

behalf.

A 16-year-old female subject received first dose of blinded study vaccine (BNT162; PLACEBO) on 07Oct2020 at 12:09 and second dose on 27Oct2020 at 14:25, both intramuscularly at left deltoid as single dose for COVID-19 immunization. Ongoing medical history included right ankle fracture from 11Sep2020, obesity from 2019 and charcot marie tooth from 2005. Other medical history included right achilles release in 2011 and 2013. Concomitant drugs, concomitant vaccines and prior vaccinations (within 4 weeks) were none. Family medical history relevant to the event was not applicable. On 15Nov2020, the subject experienced right lower extremity deep vein thrombosis (DVT) which caused hospitalization for 5 days. Clinical course was as follows: subject was admitted to hospital on 15Nov2020 for a right lower extremity DVT. Subject was discharged on 1 mg of enoxaparin sodium (LOVENOX) twice daily (BID) for 90 days per subject's parent. The action taken for the blinded study vaccine in response to the event was not applicable. Outcome of the event was recovering.

The investigator considered there was not a reasonable possibility that the event right lower extremity DVT was related to the blinded study vaccine or clinical trial procedure.

Follow-up (28Dec2020): New information reported includes: reaction data (updated from 'left lower extremity DVT' to 'right lower extremity DVT').

Follow-up (08Feb2021): New information reported includes: additional medical history.

Case Comment: The company reasonably does not attribute the case to blinded study vaccine, (BNT162;PLACEBO) or clinical trial procedure based on the pathophysiology of the event. The event is most likely coincidental and associated with underlying clinical conditions.

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
07-OCT-2020 to 07-OCT-2020	Historical Vaccine	BNT162;PLACEBO (BLINDED THERAPY); Drug Indication: COVID-19 immunization (COVID-19 immunisation) solution for injection, dose 1, IM, deltoid left, at time 12:09
2019 to Ongoing	Relevant Med History	Obesity (Obesity);
2005 to Ongoing	Relevant Med History	Charcot-Marie-Tooth disease (Hereditary motor and sensory neuropathy);
2011 to 2011	Relevant Med History Right achilles release	Tenotomy (Tenotomy);
2013 to 2013	Relevant Med History Right achilles release	Tenotomy (Tenotomy);

25b. Name And Address of Reporters continued

Michael Dever MD

UNITED STATES

Chanel Adams ARNP

UNITED STATES

Rebecca Klipper
618 E South Street
Orlando, FL 32801
UNITED STATES

Beckie Klipper

02-May-2021 13:14

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ADDITIONAL INFORMATION

UNITED STATES

090177e196eff2f2\Final\Final On: 03-May-2021 12:32 (GMT)

SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last) PRIVACY	1a. COUNTRY UNITED STATES	2. DATE OF BIRTH Day Month Year (b) (6) 1967	2a. AGE 53 Years	3. SEX Male	3a. WEIGHT 113.83 kg	4-6 REACTION ONSET Day Month Year 27 DEC 2020	8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION <input type="checkbox"/> PATIENT DIED <input checked="" type="checkbox"/> INVOLVED OR PROLONGED INPATIENT HOSPITALISATION <input type="checkbox"/> INVOLVED PERSISTENT OR SIGNIFICANT DISABILITY OR INCAPACITY <input type="checkbox"/> LIFE THREATENING
7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data) Event Verbatim [PREFERRED TERM] (Related symptoms if any separated by commas) Other Serious Criteria: Medically Significant bilateral DVT [Deep vein thrombosis] pulmonary embolism [Pulmonary embolism] Case Description: A PHASE 1/2/3, PLACEBO-CONTROLLED, RANDOMIZED, OBSERVER-BLIND, DOSE-FINDING STUDY TO EVALUATE THE SAFETY, TOLERABILITY, IMMUNOGENICITY, AND EFFICACY OF SARS-COV-2 RNA VACCINE CANDIDATES AGAINST COVID-19 IN HEALTHY INDIVIDUALS							

(Continued on Additional Information Page)

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name) #1) BNT162;PLACEBO (Code not broken)	20. DID REACTION ABATE AFTER STOPPING DRUG? <input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> NA
15. DAILY DOSE(S) Blinded, Information withheld.	16. ROUTE(S) OF ADMINISTRATION Blinded, Information withheld.
17. INDICATION(S) FOR USE #1) COVID-19 immunization (COVID-19 immunisation)	21. DID REACTION REAPPEAR AFTER REINTRODUCTION? <input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> NA
18. THERAPY DATES(from/to) #1) 04-SEP-2020 11:42:00 / 04-SEP-2020 11:42:00	19. THERAPY DURATION #1) Unknown

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction) #1) NORVASC (AMLODIPINE BESILATE) ; DEC-2020 / Ongoing #2) ATENOLOL (ATENOLOL) ; DEC-2020 / Ongoing #3) CLONAZEPAM (CLONAZEPAM) ; 2009 / Ongoing #4) TRAZODONE HCL (TRAZODONE HCL) ; 2009 / Ongoing #5) AMBIEN (ZOLPIDEM TARTRATE) ; 2009 / Ongoing #6) TRINTELLIX (VORTIOXETINE HYDROBROMIDE) ; 2009 / Ongoing	
23. OTHER RELEVANT HISTORY. (e.g. diagnostics, allergies, pregnancy with last month of period, etc.) From/To Dates 14-AUG-2020 to 14-AUG-2020 2018 to 2018	Type of History / Notes Historical Vaccine First dose: IM in left deltoid at 12:50 Relevant Med History Hip replacement (Hip arthroplasty) total left hip replacement.; Not relevant medical history for recent PE and bilateral DVT.

(Continued on Additional Information Page)

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER Pfizer Inc Head Drug Safety Surveillance 219 East 42nd Street New York, New York 10017 UNITED STATES Phone: 212 733 5544	26. REMARKS
24b. MFR CONTROL NO. 2021008512	25b. NAME AND ADDRESS OF REPORTER Edward Walsh MD
24c. DATE RECEIVED BY MANUFACTURER 29-APR-2021	24d. REPORT SOURCE <input checked="" type="checkbox"/> STUDY <input type="checkbox"/> LITERATURE <input checked="" type="checkbox"/> HEALTH PROFESSIONAL <input type="checkbox"/> OTHER:
DATE OF THIS REPORT 02-MAY-2021	25a. REPORT TYPE <input type="checkbox"/> INITIAL <input type="checkbox"/> FOLLOWUP:

ADDITIONAL INFORMATION**7+13. DESCRIBE REACTION(S) continued**

This is a report from an interventional study source for Protocol C4591001 sponsored by BioNTech, managed and reported by Pfizer on the sponsor's behalf.

A 53-year-old male subject received the first dose of the blinded study vaccine (BNT162;PLACEBO) on 14Aug2020 at 12:50 and second dose on 04Sep2020 at 11:42, both intramuscularly in the left deltoid as single doses for COVID-19 immunization. The subject took both doses of the blinded study vaccine without problem. The subject was unblinded on 28Jan2021 to provide the opportunity of receiving COVID-19 vaccine per protocol. The subject was confirmed to be in IMP arm and received BNT162b2. The subject received the third dose BNT162b2 30 mcg or BNT162b2SA (booster Visit 301) on 31Mar2021 at 17:26 intramuscularly in the left deltoid for COVID-19 immunization. The subject had a medical history of left hip replacement in 2018 which was considered as not relevant medical history for recent events pulmonary embolism (PE) and bilateral deep vein thrombosis (DVT). Ongoing medical history included PE/DVT from 2007 (IVC filter Coumadin), seizure disorder, pulmonary hypertension (HTN), hyperlipidemia, sleep apnea from 2009 with continuous positive airway pressure (CPAP), depression with medication therapy, post-traumatic stress disorder (PTSD) from 2009 with medication therapy, insomnia from 2009 with medication therapy, and unreliable medical historian from 14Aug2020 (Compared medical chart with subjects verbal report on 20Apr2021). Other medical history included pulmonary sarcoidosis (in remission), suicidal ideation in 2009 (not currently), substance abuse. Ongoing concomitant medications included amlodipine besilate (NORVASC) and atenolol from Dec2020 for HTN, clonazepam from 2009 for PTSD, trazodone hcl and zolpidem tartrate (AMBIEN) from 2009 for insomnia, vortioxetine hydrobromide (TRINTELLIX) from 2009 for depression. The family medical history relevant to the adverse event was unknown. It was confirmed that atenolol and amlodipine were medications that the subject was taking before and after hospitalization. Concomitant vaccines or prior vaccinations within 4 weeks were not reported. The subject experienced bilateral DVT on 27Dec2020 and experienced pulmonary embolism on 28Dec2020, both events required a visit to the emergency room (ER) with serious criteria of important medical event and hospitalization/prolonged hospitalization. The clinical course was provided as follows: approximately on 26Dec2020, the subject developed difficulty walking due to non-specific right lower quadrant pelvic/abdominal pain. The subject was seen at the hospital ER and a computerized tomogram (CT) scan revealed several non-obstructing renal stones. The subject returned home with pain medication, but that evening his legs began to swell and he noted bulging of the superficial veins. The subject was seen the next day at another hospital ER where a repeat abdominal CT scan showed that the renal stones had passed. On 27Dec2020, an ultrasound of both legs revealed bilateral DVT and he was treated in the ER with enoxaparin (LOVENOX) ongoing from Dec2020 and discharged home. The subject also received topiramate (TOPAMAX) for DVT pain ongoing from Dec2020. Due to his concern about the care he had received and because of new dyspnea, he traveled to another hospital where he was diagnosed with bilateral pulmonary emboli on 28Dec2020 by CT of chest. On the same date, he was admitted to hospital and remained hospitalized at the time of the report on 07Jan2021. The subject apparently had a hematology consultation and was told that evaluation revealed a "protein" abnormality that was associated with clotting. Of note, the subject had no family history of clots, nor had a past history of clots. The subject had not recently travelled or been sedentary as he worked full time. There was no information available regarding the medication treatment. COVID test in the hospital on 28Dec2020 was negative. The subject also had ongoing S protein deficiency (protein abnormality) and HTN (medication therapy) both from 28Dec2020; which were not considered an SAE. The subject also reported diabetes type 2 from 28Dec2020 to 11Jan2021 (during past hospitalization). However, diabetes did not seem to be a current/valid diagnosis. Blood glucose levels were normal during recent hospitalization and was no on any medication to treat. Subject continued to recover from DVT and still had complaints of leg swelling and leg pain. Subject was discharged from hospital on 11Jan2021. Discharge medication included warfarin sodium (COUMADIN) 1.5 tablets 6 days per week and 1 tab 1 day per week. Next appointment for subject was 03Mar2021. It was reported that the subject continued to have blood clots. On 14Apr2021, the subject was admitted to a hospital for right lower extremity DVT shortly after his appointment with a vascular surgeon on 13Apr2021. The subject had an elective thrombolysis right lower extremity. Thrombolysis right lower extremity on 14Apr2021 was necessary as an emergent care treatment for worsening of DVT of previously reported DVT (occurring on 28Dec2020) had improvement of symptoms. The subject lab test on 15Apr2021 included international normalised ratio (INR) was 1.8 seconds (normal range 0.9 to 1.1) with comments expected due to DVT therapy, hematocrit (HCT) was 37% (normal range 40-75), reactive lymphocytes was 6% (normal range 0-0), neutrophils was 24% (normal range 45-75), factor V Leiden results was positive at 3.4 with comments positive parameters 1.2 to 2.0; Beta-2 glycoprotein Ab, cardiolipin Ab, IgG, IgM and prothrombin G20210A mutation; were all confirmed with negative results. On 16Apr2021, the subject was discharged home feeling better and resting. The action taken in response to the event for the blinded study vaccine was not applicable. The outcome of the event pulmonary embolism was recovered on 11Jan2021 while the outcome of the event bilateral DVT was recovering.

The investigator considered there was not a reasonable possibility that the events pulmonary embolism and bilateral DVT were related to blinded study vaccine, concomitant medications or clinical trial procedure. As per the investigator, based on the history, the subject appeared to have a hereditary or acquired protein abnormality that was associated with and predisposed him to the development of deep venous thrombosis and pulmonary emboli.

Follow-up (08Jan2021 and 11Jan2021): New information reported includes: reaction data (the SAE onset date was updated to 27Dec2020), study drug details (administration date of second dose updated), relevant medical history updated, lab data added and clinical course (hospitalization date and no information about the medication treatment).

Follow-up (21Jan2021): New information reported includes: SAE onset date and outcome updated, relevant test, discharge date and discharge medications, and blinded study vaccine second dose date.

Follow-up (04Feb2021, 08Feb2021 and 09Feb2021): This is a follow-up report combining information from duplicate reports AER 2021008512 and 2021018790. The current and all subsequent follow-up information will be reported under manufacturer report

ADDITIONAL INFORMATION**7+13. DESCRIBE REACTION(S) continued**

number 2021008512. New information reported includes: reaction data (additional event "bilateral DVT"; outcome of event "pulmonary embolism"), clinical course and S protein deficiency (protein abnormality) was adverse event.

Follow-up (12Feb2021 and 15Feb2021): New information reported includes: adverse reaction (confirmed event pulmonary embolism onset date and outcome of event bilateral DVT updated to recovered).

Follow-up (23Feb2021): New information reported includes: reaction data (added seriousness criteria prolonged hospitalization of the event bilateral DVT).

Follow-up (05Mar2021): New information reported includes: Serious criteria 'important medical event' added for the event pulmonary embolism and updated medical history and clinical course.

Follow-up (15Apr2021 and 19Apr2021): New information reported includes: study drug information, reaction data (outcome of the event bilateral DVT updated to recovering), medical history and clinical course (treatment information and procedures).

Follow-up (23Apr2021): New information reported includes: medical history, lab tests and concomitant medications, treatments.

Follow-up (29Apr2021): New information reported includes: clinical course (HTN not an SAE), concomitant medication information and laboratory data.

Case Comment: The company reasonably does not attribute the case to blinded study vaccine, (BNT162;PLACEBO) concomitant drugs or clinical trial procedure based on the pathophysiology of the events and the latency.

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1	15-APR-2021	Beta-2 glycoprotein antibody Negative results are positive or negative	Negative	
2		Blood glucose during recent hospitalization and was no on any medication to treat	normal	
3	15-APR-2021	Cardiolipin antibody Negative results are positive or negative	Negative	
4		Computerised tomogram	several non-obstructing renal stones	
5		Computerised tomogram abdomen	renal stones had passed	
6	28-DEC-2020	Computerised tomogram thorax	Revealed bilateral pulmonary emboli (PE)	
7	15-APR-2021	Factor II mutation Negative results are positive or negative	Negative	
8	15-APR-2021	Factor V Leiden carrier Positive positive parameters 1.2 to 2.0	positive at 3.4	
9	15-APR-2021	Haematocrit	37 %	75 40
10		Haematology test protein abnormality that was associated with clotting	protein abnormality	
11	15-APR-2021	International normalised ratio expected due to DVT therapy	1.8 seconds	1.1 0.9

ADDITIONAL INFORMATION**13. Lab Data**

#	Date	Test / Assessment / Notes	Results	Normal High / Low
12	15-APR-2021	Lymphocyte count	6 %	0 0
13	15-APR-2021	Neutrophil count	24 %	75 45
14	28-DEC-2020	SARS-CoV-2 test Negative	negative	
15	27-DEC-2020	Ultrasound scan	Revealed bilateral DVT	

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
14-AUG-2020 to 14-AUG-2020	Historical Vaccine	BNT162;PLACEBO (BNT162B2); Drug Indication: COVID-19 immunization (COVID-19 immunisation) First dose: IM in left deltoid at 12:50
2007 to Ongoing	Relevant Med History IVC filter Coumadin	Pulmonary embolism (Pulmonary embolism);
2007 to Ongoing	Relevant Med History IVC filter Coumadin	DVT (Deep vein thrombosis);
Unknown to Ongoing	Relevant Med History disorder	Seizure (Seizure);
Unknown to Ongoing	Relevant Med History	Pulmonary hypertension (Pulmonary hypertension);
Unknown to Ongoing	Relevant Med History	Hyperlipidemia (Hyperlipidaemia);
Unknown	Relevant Med History in remission	Pulmonary sarcoidosis (Pulmonary sarcoidosis);
2009 to Ongoing	Relevant Med History CPAP	Sleep apnea (Sleep apnoea syndrome);
Unknown	Relevant Med History	CPAP (Continuous positive airway pressure);
Unknown to Ongoing	Relevant Med History medication therapy	Depression (Depression);
2009 to Ongoing	Relevant Med History medication therapy	Post-traumatic stress disorder (Post-traumatic stress disorder);
2009 to Ongoing	Relevant Med History medication therapy	Insomnia (Insomnia);
2009 to 2009	Relevant Med History not currently	Suicidal ideation (Suicidal ideation);
Unknown	Relevant Med History	Substance abuse (Substance abuse);

SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last) PRIVACY	1a. COUNTRY UNITED STATES	2. DATE OF BIRTH Day Month Year (b) (6) 2007	2a. AGE 13 Years	3. SEX Female	3a. WEIGHT 67.12 kg	4-6 REACTION ONSET Day Month Year 23 DEC 2020	8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data) Event Verbatim [PREFERRED TERM] (Related symptoms if any separated by commas) worsening of anxiety [Anxiety] worsening of depression [Depression] Case Description: A PHASE 1/2/3, PLACEBO-CONTROLLED, RANDOMIZED, OBSERVER-BLIND, DOSE-FINDING STUDY TO EVALUATE THE SAFETY, TOLERABILITY, IMMUNOGENICITY, AND EFFICACY OF SARS-COV-2 RNA VACCINE CANDIDATES AGAINST COVID-19 IN HEALTHY INDIVIDUALS This is a report from an interventional study source for Protocol							<input type="checkbox"/> PATIENT DIED <input checked="" type="checkbox"/> INVOLVED OR PROLONGED INPATIENT HOSPITALISATION <input type="checkbox"/> INVOLVED PERSISTENT OR SIGNIFICANT DISABILITY OR INCAPACITY <input type="checkbox"/> LIFE THREATENING

(Continued on Additional Information Page)

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name) #1) BNT162;PLACEBO (Code not broken)	20. DID REACTION ABATE AFTER STOPPING DRUG? <input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> NA
15. DAILY DOSE(S) Blinded, Information withheld.	16. ROUTE(S) OF ADMINISTRATION Blinded, Information withheld.
17. INDICATION(S) FOR USE #1) COVID-19 immunization (COVID-19 immunisation)	21. DID REACTION REAPPEAR AFTER REINTRODUCTION? <input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> NA
18. THERAPY DATES(from/to) #1) 16-DEC-2020 12:07:00 / 16-DEC-2020 12:07:00	19. THERAPY DURATION #1) Unknown

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction) #1) CELEXA [CITALOPRAM HYDROBROMIDE] (CITALOPRAM HYDROBR #2) CYMBALTA (DULOXETINE HYDROCHLORIDE) Tablet ; 2019 / 30-DEC-2020 #3) SINGULAIR (MONTELUKAST SODIUM) Tablet ; 2013 / 30-DEC-2020 #4) VENTOLIN [SALBUTAMOL] (SALBUTAMOL) ; 2013 / Ongoing #5) FLOVENT (FLUTICASONE PROPIONATE) ; 2013 / Ongoing	
(Continued on Additional Information Page)	
23. OTHER RELEVANT HISTORY. (e.g. diagnostics, allergies, pregnancy with last month of period, etc.) From/To Dates 2010 to Ongoing 2014 to Ongoing	Type of History / Notes Relevant Med History Relevant Med History Description Depression (Depression)
(Continued on Additional Information Page)	

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER Pfizer Inc Head Drug Safety Surveillance 219 East 42nd Street New York, New York 10017 UNITED STATES Phone: 212 733 5544	26. REMARKS
24b. MFR CONTROL NO. 2021009347	25b. NAME AND ADDRESS OF REPORTER James Peterson MD
24c. DATE RECEIVED BY MANUFACTURER 24-FEB-2021	25d. REPORT SOURCE <input checked="" type="checkbox"/> STUDY <input type="checkbox"/> LITERATURE <input checked="" type="checkbox"/> HEALTH PROFESSIONAL <input type="checkbox"/> OTHER:
DATE OF THIS REPORT 02-MAY-2021	25a. REPORT TYPE <input type="checkbox"/> INITIAL <input type="checkbox"/> FOLLOWUP:
UNITED STATES (b) (6) UNITED STATES (Continued on Additional Information Page)	

ADDITIONAL INFORMATION**7+13. DESCRIBE REACTION(S) continued**

C4591001 sponsored by BioNTech, managed and reported by Pfizer on the sponsor's behalf.

A 13-year-old female subject received first dose of blinded study vaccine (BNT162;PLACEBO) on 16Dec2020 at 12:07, via intramuscular (IM) route at left deltoid as single doses for COVID-19 immunization. Ongoing medical history included attention deficit hyperactivity disorder from 2010, separation anxiety disorder from 2010, disruptive mood dysregulation disorder from 2012, asthma moderate from 2013, depression and anxiety from 2014, recurring insomnia from 2014, recurring nightmares from 2015, and post-traumatic stress disorder from 16Nov2015. Other medical history included aggressive behavior in 2017 for which the subject was hospitalized for 4 days in 2017. Family medical history included post-traumatic stress disorder, border line personality disorder (b) (6) and drug addiction (b) (6). Concomitant medications included citalopram hydrobromide (CELEXA) for depression from Oct2020 to 30Dec2020, duloxetine hydrochloride (CYMBALTA) for depression from 2019 to 30Dec2020, montelukast sodium (SINGULAIR) for asthma from 2013 to 30Dec2020, salbutamol (VENTOLIN) (reported as albuterol) for asthma from 2013 and ongoing, and fluticasone propionate (FLOVENT) for asthma from 2013 and ongoing. The subject had no concomitant vaccines or prior vaccines (within 4 weeks). The subject experienced worsening of anxiety and worsening of depression on 23Dec2020 which required a visit to physician office but not to emergency room and resulted in hospitalization for 14 days. The clinical course was the following: subject had a medical history of anxiety and depression; both were stable at visit 1. After visit 1, subject experienced a worsening of anxiety and a worsening of depression. She was seen by physician who prescribed aripiprazole (ABILIFY) 1mg and venlafaxine 150mg per day which was started on 30Dec2020. The physician also recommended that subject be admitted to in-patient residential treatment/ psychiatric facility for medical management and stabilization. She was admitted on 05Jan2021. Subject was not tested for COVID-19 prior to admission to facility and was not been tested since admission per subject's legal guardian. There were no relevant tests. During their most recent scheduled visit, the subject and guardian stated that the subject's mental health had stabilized, and the subject was discharged on 18Jan2021. The subject and guardian reported starting trazodone 50mg every night on 06Jan2021 to treat her medical history of recurring insomnia. Otherwise, denies any changes. The action taken regarding the study drug for the events was permanently withdrawn, second dose was not given. Outcome of the events was recovered on 18Jan2021.

The investigator considered there was not a reasonable possibility that the events worsening of anxiety and worsening of depression were related to the blinded vaccine, concomitant medications or clinical trial procedure.

Follow-up (08Jan2021): New information reported includes: additional reporter added.

Follow-up (14Jan2021): New information reported includes: lab data details updated.

Follow-up (21Jan2021): New information reported includes: additional medical history and family medical history.

Follow-up (24Feb2021): New information reported includes: reaction data (outcome), hospitalization details, treatment details and clinical course (event details).

Case Comment: The company reasonably does not attribute the case to blinded study vaccine, (BNT162;PLACEBO) concomitant drugs or clinical trial procedure based on the information currently available.

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION continued

#1) CELEXA [CITALOPRAM HYDROBROMIDE] (CITALOPRAM HYDROBROMIDE) Tablet ; OCT-2020 / 30-DEC-2020

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
2010 to Ongoing	Relevant Med History	Attention deficit hyperactivity disorder (Attention deficit hyperactivity disorder);
2014 to Ongoing	Relevant Med History	Anxiety (Anxiety);
2013 to Ongoing	Relevant Med History moderate	Asthma (Asthma);
16-NOV-2015 to Ongoing	Relevant Med History	Post-traumatic stress disorder (Post-traumatic stress disorder);
2012 to Ongoing	Relevant Med History	Disruptive mood dysregulation disorder (Disruptive mood

ADDITIONAL INFORMATION**23. OTHER RELEVANT HISTORY continued**

From/To Dates	Type of History / Notes	Description
		dysregulation disorder);
2010 to Ongoing	Relevant Med History	Separation anxiety disorder (Separation anxiety disorder);
2014 to Ongoing	Relevant Med History recurring	Insomnia exacerbated (Insomnia);
2017 to 2017	Relevant Med History hospitalized for 4 days in 2017	Aggressive behavior (Aggression);
2015 to Ongoing	Relevant Med History recurring	Nightmares (Nightmare);
Unknown	Relevant Med History (b) (6) border line personality disorder	Post-traumatic stress disorder (Post-traumatic stress disorder);
Unknown	Relevant Med History (b) (6)	Personality disorder (Personality disorder);
Unknown	Relevant Med History (b) (6)	Drug addiction (Drug dependence);

25b. Name And Address of Reporters continued
James Peterson MD

UNITED STATES

(b) (6)

UNITED STATES

(b) (6)

(b) (6)

Alexander Clark DO

UNITED STATES

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SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last) PRIVACY	1a. COUNTRY BRAZIL	2. DATE OF BIRTH			2a. AGE 51 Years	3. SEX Female	3a. WEIGHT 103.00 kg	4-6 REACTION ONSET			8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION <input type="checkbox"/> PATIENT DIED <input checked="" type="checkbox"/> INVOLVED OR PROLONGED INPATIENT HOSPITALISATION <input type="checkbox"/> INVOLVED PERSISTENT OR SIGNIFICANT DISABILITY OR INCAPACITY <input type="checkbox"/> LIFE THREATENING
		Day	Month	Year			Day	Month	Year		
		(b) (6)	(6)	1969			05	JAN	2021		

7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data)
Event Verbatim [LOWER LEVEL TERM] (Related symptoms if any separated by commas)
deep venous thrombosis in right lower limb [Thrombosis of leg deep venous]

Case Description: A PHASE 1/2/3, PLACEBO-CONTROLLED, RANDOMIZED, OBSERVER-BLIND, DOSE-FINDING STUDY TO EVALUATE THE SAFETY, TOLERABILITY, IMMUNOGENICITY, AND EFFICACY OF SARS-COV-2 RNA VACCINE CANDIDATES AGAINST COVID-19 IN HEALTHY INDIVIDUALS.

This is a report from an interventional study source for Protocol C4591001 sponsored by BioNTech, managed and reported by Pfizer on the Sponsor's

(Continued on Additional Information Page)

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name) #1) BNT162;PLACEBO (Code not broken)		20. DID REACTION ABATE AFTER STOPPING DRUG? <input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> NA
15. DAILY DOSE(S) Blinded, Information withheld.	16. ROUTE(S) OF ADMINISTRATION Blinded, Information withheld.	
17. INDICATION(S) FOR USE #1) Covid-19 immunization (COVID-19 immunisation)		21. DID REACTION REAPPEAR AFTER REINTRODUCTION? <input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> NA
18. THERAPY DATES(from/to) #1) 26-OCT-2020 11:49:00 / 26-OCT-2020 11:49:00	19. THERAPY DURATION #1) Unknown	

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)	
23. OTHER RELEVANT HISTORY. (e.g. diagnostics, allergies, pregnancy with last month of period, etc.) From/To Dates Type of History / Notes Description 03-OCT-2020 to 03-OCT-2020 Historical Vaccine Dose 1 on 03Oct2020 12:05 via IM at left deltoid 1999 to 1999 Relevant Med History Pulmonary thromboembolism (Pulmonary embolism)	

(Continued on Additional Information Page)

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER Laboratórios Pfizer Ltda (b) (6) Rua Alexandre Dumas, 1860 Chácara Santo Antonio, São Paulo, 04717-904 BRAZIL		26. REMARKS
	24b. MFR CONTROL NO. 2021159077	
24c. DATE RECEIVED BY MANUFACTURER 02-MAR-2021	24d. REPORT SOURCE <input checked="" type="checkbox"/> STUDY <input type="checkbox"/> LITERATURE <input checked="" type="checkbox"/> HEALTH PROFESSIONAL <input type="checkbox"/> OTHER:	
DATE OF THIS REPORT 02-MAY-2021	25a. REPORT TYPE <input type="checkbox"/> INITIAL <input type="checkbox"/> FOLLOWUP:	

25b. NAME AND ADDRESS OF REPORTER
NAME AND ADDRESS WITHHELD.

NAME AND ADDRESS WITHHELD.

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

behalf.

A 51-year-old female subject started to receive first dose blinded therapy (BNT162; PLACEBO) on 03Oct2020 at 12:05 and second dose on 26Oct2020 at 11:49, both intramuscularly at left deltoid at single dose for Covid-19 immunization. Then the subject was unblinded on 10Feb2021 to provide the opportunity of receiving COVID-19 vaccine per protocol, she received BNT162b2 (Lot number P2203950022L; expiration date Jun2021) as the third dose on 13Feb2021 at 13:00 via intramuscular at left deltoid at single dose for Covid-19 immunization. Medical history included pulmonary thromboembolism (PTE) in 1999. No family medical history relevant to AEs. There was no concomitant drugs and concomitant vaccines received. No prior vaccinations (within 4 weeks) was given. On 05Jan2021, the subject experienced deep venous thrombosis in right lower limb which required hospitalization for 2 days and a visit to emergency room. Subject reported that on 05Jan2021 she started with pain in his right lower limb, which evolved to edema and increased temperature in the calf region. On 09Jan2021, she was evaluated by the vascular doctor who diagnosed it as deep venous thrombosis (DVT), performing on that same day the ultrasound exam with doppler of the lower limb, which confirmed the previous diagnosis. Reverse transcription polymerase chain reaction (RT-PCR) exam was performed on 09Jan2021 with a negative result for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (not detected). She was hospitalized between 11Jan2021 and 13Jan2021 for placement of a vena cava filter. Doppler ultrasound of lower limb arteries and veins was performed, on 07Jan2021, showed deep venous thrombosis in the common femoral vein, femoral vein and popliteal vein in the right lower limb which confirmed the diagnosis of deep venous thrombosis in the right lower limb. Another ultrasound of lower limb veins was performed after placing the filter in the right vena cava, on 11Jan2021, that indicates signs of partially recanalized venous thrombosis in the right lower limb. The possible cause was reduced mobility due to quarantine, according to her vascular surgeon. Subject stated that he used enoxaparin sodium (CLEXANE) 100 milligrams 2 times a day (subcutaneously) from 09Jan2021 to 05Feb2021 and since 06Feb2021 she was using rivaroxaban (XARELTO) 20 milligrams 1 time a day (orally). She mentioned that in 1999, she had an episode of pulmonary thromboembolism (PTE). Subject informed that at the time there was an investigation of this condition, but no cause was found. In principle, DVT and PTE were not related. The DVT was stable and subject reported that on doppler ultrasound performed on 11Jan2021, it demonstrated partial recanalization. The action taken in response to the event for blinded therapy was not applicable. The outcome of event was recovered on 13Jan2021, but the event of deep venous thrombosis in the right lower limb remains present as a non-serious event.

The investigator considered there was not a reasonable possibility that the event deep venous thrombosis in right lower limb was related to blinded study vaccine (BNT162;PLACEBO) or to clinical trial procedures.

Follow-up (22Feb2021 and 25Feb2021): New information reported includes updated lab data, study drug details (unblinding date), reaction data (SAE term updated from "Deep vein thrombosis" to "deep venous thrombosis in right lower limb", onset date and recovery date updated) and clinical course (hospitalization dates and event's current status).

Follow-up (02Mar2021): New information reported includes: lab test updated (RT-PCR).

Case Comment: The company reasonably does not attribute the case to study product, concomitant drugs or clinical trial procedure.

13. Lab Data

#	Date	Test / Assessment / Notes	Results	Normal High / Low
1	05-JAN-2021	Body temperature	increased	
2	01-JAN-2021	Polymerase chain reaction Negative for SARS-CoV-2	not detected	
3	07-JAN-2021	Ultrasound Doppler deep venous thrombosis in the common femoral vein, femoral vein and popliteal vein in the right lower limb. Confirm the diagnosis of deep venous thrombosis in the right lower limb.	deep venous thrombosis in the common femoral vein, deep venous thrombosis in the common femoral vein, femoral vein and popliteal vein in the right lower limb. Confirm the diagnosis of deep venous thrombosis in the right lower limb.	
4	09-JAN-2021	Ultrasound Doppler	deep venous thrombosis	
5	11-JAN-2021	Ultrasound Doppler	partial recanalization	
6	11-JAN-2021	Ultrasound Doppler	signs of partially recanalized venous thrombosis i	

ADDITIONAL INFORMATION**13. Lab Data**

#	Date	Test / Assessment / Notes	Results	Normal High / Low
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signs of partially recanalized venous thrombosis in the right lower limb.

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
03-OCT-2020 to 03-OCT-2020	Historical Vaccine	BNT162:PLACEBO (BLINDED THERAPY); Drug Indication: COVID-19 immunization (COVID-19 immunisation) Dose 1 on 03Oct2020 12:05 via IM at left deltoid

090177e196eff2f2\Final\Final On: 03-May-2021 12:32 (GMT)

SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last) PRIVACY	1a. COUNTRY UNITED STATES	2. DATE OF BIRTH Day Month Year (b) (6) 2006	2a. AGE 14 Years	3. SEX Female	3a. WEIGHT 50.70 kg	4-6 REACTION ONSET Day Month Year 19 JAN 2021	8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data) Event Verbatim [PREFERRED TERM] (Related symptoms if any separated by commas) worsening of depression [Depression] Case Description: PHASE 1/2/3, PLACEBO-CONTROLLED, RANDOMIZED, OBSERVER-BLIND, DOSE-FINDING STUDY TO EVALUATE THE SAFETY, TOLERABILITY, IMMUNOGENICITY, AND EFFICACY OF SARS-COV-2 RNA VACCINE CANDIDATES AGAINST COVID-19 IN HEALTHY INDIVIDUALS This is a report from an interventional study source for Protocol C4591001 sponsored by BioNTech, managed and reported by Pfizer on the sponsor's							<input type="checkbox"/> PATIENT DIED <input checked="" type="checkbox"/> INVOLVED OR PROLONGED INPATIENT HOSPITALISATION <input type="checkbox"/> INVOLVED PERSISTENT OR SIGNIFICANT DISABILITY OR INCAPACITY <input type="checkbox"/> LIFE THREATENING

(Continued on Additional Information Page)

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name) #1) BNT162;PLACEBO (Code not broken)	20. DID REACTION ABATE AFTER STOPPING DRUG? <input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> NA
15. DAILY DOSE(S) Blinded, Information withheld.	16. ROUTE(S) OF ADMINISTRATION Blinded, Information withheld.
17. INDICATION(S) FOR USE #1) Covid-19 immunization (COVID-19 immunisation)	21. DID REACTION REAPPEAR AFTER REINTRODUCTION? <input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> NA
18. THERAPY DATES(from/to) #1) 18-JAN-2021 11:50:00 / 18-JAN-2021 11:50:00	19. THERAPY DURATION #1) Unknown

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction) #1) PROZAC (FLUOXETINE HYDROCHLORIDE) ; NOV-2020 / Ongoing #2) ZYRTEC [CETIRIZINE HYDROCHLORIDE] (CETIRIZINE HYDROCHLORIDE) #3) ADDERALL (AMFETAMINE ASPARTATE, AMFETAMINE SULFATE, #4) ALMOTRIPTAN (ALMOTRIPTAN) ; 2015 / Ongoing	
(Continued on Additional Information Page)	
23. OTHER RELEVANT HISTORY. (e.g. diagnostics, allergies, pregnancy with last month of period, etc.) From/To Dates 28-DEC-2020 to 28-DEC-2020 OCT-2018 to Ongoing	Type of History / Notes Historical Vaccine Dose 1 IM at deltoid left on 28Dec2020 at 16:52 Relevant Med History Description Anxiety (Anxiety)
(Continued on Additional Information Page)	

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER Pfizer Inc Head Drug Safety Surveillance 219 East 42nd Street New York, New York 10017 UNITED STATES Phone: 212 733 5544	26. REMARKS
24b. MFR CONTROL NO. 2021168083	25b. NAME AND ADDRESS OF REPORTER Brandon Essink
24c. DATE RECEIVED BY MANUFACTURER 05-MAR-2021	24d. REPORT SOURCE <input checked="" type="checkbox"/> STUDY <input type="checkbox"/> LITERATURE <input checked="" type="checkbox"/> HEALTH PROFESSIONAL <input type="checkbox"/> OTHER:
DATE OF THIS REPORT 02-MAY-2021	25a. REPORT TYPE <input type="checkbox"/> INITIAL <input type="checkbox"/> FOLLOWUP:

ADDITIONAL INFORMATION**7+13. DESCRIBE REACTION(S) continued**

behalf.

A 14-year-old female subject received first dose of blinded study vaccine (BNT162:PLACEBO) on 28Dec2020 at 16:52, and second dose 18Jan2021 at 11:50, both via intramuscular (IM) route at deltoid left at single dose for covid-19 immunization. Medical history included seasonal allergies from 2008, attention deficit hyperactivity disorder from 2013, migraine from 2015, anxiety from Oct2018, and depression from Oct2018, all ongoing. Ongoing concomitant medications included amphetamine aspartate/amphetamine sulfate/dexamphetamine saccharate/dexamphetamine sulfate (ADDERALL) for attention deficit hyperactivity disorder from 2013, almotriptan for migraines from 2015, cetirizine hydrochloride (ZYRTEC) for seasonal allergies from 2018, and fluoxetine hydrochloride (PROZAC) for depression and anxiety from Nov2020. The subject had no concomitant vaccines on same date of the investigational vaccines or prior vaccines (within 4 weeks). The subject experienced worsening of depression on 19Jan2021, which was serious due to hospitalization and required a visit to emergency room. The clinical course was following: The subject admitted to hospital on 19Jan2021 for worsening of depression. Subject was released from hospital on 23Jan2021. The action taken in response to the event for the blinded study vaccine was not applicable. The outcome of the event was recovered on 23Jan2021.

The investigator considered there was not a reasonable possibility that the event worsening of depression was related to blinded study vaccine, concomitant drugs or clinical trial procedure.

Follow-up (05Mar2021): New information reported includes: Updated concomitant medication (indication), and reaction data (outcome to recovered and date of recovery).

Case Comment: The company reasonably does not attribute the case to blinded study vaccine, (BNT162:PLACEBO), concomitant drugs or clinical trial procedure based on the pathophysiology of the event.

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION continued

#2) ZYRTEC [CETIRIZINE HYDROCHLORIDE] (CETIRIZINE HYDROCHLORIDE) ; 2018 / Ongoing

#3) ADDERALL (AMFETAMINE ASPARTATE, AMFETAMINE SULFATE, DEXAMFETAMINE SACCHARATE, DEXAMFETAMINE SULFATE) ; 2013 / Ongoing

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
28-DEC-2020 to 28-DEC-2020	Historical Vaccine	BNT162; PLACEBO (BLINDED THERAPY); Drug Indication: COVID-19 immunization (COVID-19 immunisation) Dose 1 IM at deltoid left on 28Dec2020 at 16:52
OCT-2018 to Ongoing	Relevant Med History	Depression (Depression);
2008 to Ongoing	Relevant Med History	Seasonal allergy (Seasonal allergy);
2013 to Ongoing	Relevant Med History	Attention deficit hyperactivity disorder (Attention deficit hyperactivity disorder);
2015 to Ongoing	Relevant Med History	Migraine (Migraine);

SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last) PRIVACY	1a. COUNTRY UNITED STATES	2. DATE OF BIRTH Day Month Year (b) (6) 2006	2a. AGE 14 Years	3. SEX Female	3a. WEIGHT 58.50 kg	4-6 REACTION ONSET Day Month Year 16 FEB 2021	8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data) Event Verbatim [PREFERRED TERM] (Related symptoms if any separated by commas) suicidal ideation [Suicidal ideation] Case Description: A PHASE 1/2/3, PLACEBO-CONTROLLED, RANDOMIZED, OBSERVER-BLIND, DOSE-FINDING STUDY TO EVALUATE THE SAFETY, TOLERABILITY, IMMUNOGENICITY, AND EFFICACY OF SARS-COV-2 RNA VACCINE CANDIDATES AGAINST COVID-19 IN HEALTHY INDIVIDUALS This is a report from an interventional study source for Protocol C4591001 sponsored by BioNTech, managed and reported by Pfizer on the sponsor's							<input type="checkbox"/> PATIENT DIED <input checked="" type="checkbox"/> INVOLVED OR PROLONGED INPATIENT HOSPITALISATION <input type="checkbox"/> INVOLVED PERSISTENT OR SIGNIFICANT DISABILITY OR INCAPACITY <input type="checkbox"/> LIFE THREATENING

(Continued on Additional Information Page)

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name) #1) BNT162;PLACEBO (Code not broken)		20. DID REACTION ABATE AFTER STOPPING DRUG? <input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> NA
15. DAILY DOSE(S) Blinded, Information withheld.	16. ROUTE(S) OF ADMINISTRATION Blinded, Information withheld.	
17. INDICATION(S) FOR USE #1) COVID-19 immunization (COVID-19 immunisation)		21. DID REACTION REAPPEAR AFTER REINTRODUCTION? <input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> NA
18. THERAPY DATES(from/to) #1) 08-JAN-2021 14:18:00 / 08-JAN-2021 14:18:00	19. THERAPY DURATION #1) Unknown	

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction) #1) FOCALIN [DEXMETHYLPHENIDATE HYDROCHLORIDE] (DEXMETHYLPHENIDATE HYDROCHLORIDE) Capsule ; 26-JAN-2021 / FEB-2021	
23. OTHER RELEVANT HISTORY. (e.g. diagnostics, allergies, pregnancy with last month of period, etc.) From/To Dates 18-DEC-2020 to 18-DEC-2020 01-JAN-2015 to Ongoing	Type of History / Notes Historical Vaccine Dose 1, on 18Dec2020 at 16:30 via intramuscular route at left deltoid, single dose Relevant Med History

(Continued on Additional Information Page)

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER Pfizer Inc Head Drug Safety Surveillance 219 East 42nd Street New York, New York 10017 UNITED STATES Phone: 212 733 5544		26. REMARKS
24b. MFR CONTROL NO. 2021195810	25b. NAME AND ADDRESS OF REPORTER Nicola Klein MD, PhD	
24c. DATE RECEIVED BY MANUFACTURER 21-APR-2021	24d. REPORT SOURCE <input checked="" type="checkbox"/> STUDY <input type="checkbox"/> LITERATURE <input checked="" type="checkbox"/> HEALTH PROFESSIONAL <input type="checkbox"/> OTHER:	UNITED STATES (b) (6)
DATE OF THIS REPORT 02-MAY-2021	25a. REPORT TYPE <input type="checkbox"/> INITIAL <input type="checkbox"/> FOLLOWUP:	UNITED STATES (Continued on Additional Information Page)

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

behalf.

A 14-year-old female subject received first dose of blinded vaccine therapy (BNT162:PLACEBO) on 18Dec2020 at 16:30 and second dose on 08Jan2021 at 14:18 via intramuscular route at left deltoid as single dose for COVID-19 immunization. Ongoing medical history included attention deficit hyperactivity disorder from 01Jan2015, anxiety from 31Aug2020 and depression from 08Dec2020. During the hospital admission and assessment, there was no documentation of knee pain and therefore not included in the medical history portion of this report. Family history relevant to AEs was unknown. Concomitant drug included dexamethylphenidate hydrochloride (FOCALIN) extended-release (XR) from 26Jan2021 to Feb2021 for attention deficit hyperactivity disorder. The exact stop date for dexamethylphenidate hydrochloride XR was unknown but stopped sometime during the psychiatric hospitalization in Feb2021. The subject had no concomitant vaccine or prior vaccines (within 4 weeks). The subject experienced suicidal ideation on 16Feb2021 at 10:17, which required a visit to emergency room and caused hospitalization. The clinical course was as follows: On 08Dec2020, subject had video visit with psych social worker for concentration problems and generalized anxiety due to perceived rejection issues. No suicidal ideation noted. On 12Jan2021, subject had video visit with psych social worker for ongoing concentration problem and generalized anxiety. Noted in record 'subject stated in general she was doing well and felt good'. On 26Jan2021, medication for attention deficit hyperactivity disorder changed from methylphenidate hydrochloride (CONCERTA) at 36mg orally TR24 SR Tab 1 tab daily to dexamethylphenidate hydrochloride at 5mg two capsules in the morning. Subject was experiencing side effects of anger, agitation and appetite reduction with methylphenidate hydrochloride. On 16Feb2021, mother provided secured message to primary doctor concerning that daughter told her of suicidal thoughts two weeks ago but recently found a suicide note and behavior of being more withdrawn. Mother stated about (b) (6). Mother questioned whether change in medication to dexamethylphenidate hydrochloride might be a contributing factor to behavior. On 16Feb2021, subject was admitted to emergency department for suicidal ideation and suicidal plan. On 17Feb2021, unable to engage in safety planning therefore met the criteria for 5150 intervention and transferred to an acute psychiatric hospital. The subject released from hospitalization on 23Feb2021. Now home (b) (6). Office visit on 01Mar2021, per visit note, the subject said "her suicidal thoughts was triggered by (b) (6)". 02Mar2021, the subject started on fluoxetine 10 mg, 1 capsule orally every morning for 2 weeks then increased to 2 capsules orally every morning. Continued with individual therapy and started on intensive outpatient program. Per video visit with psychiatry doctor of medicine (MD) on 02Mar2021: Mother reported that subject was on methylphenidate hydrochloride in the past but was ineffective and was prescribed dexamethylphenidate hydrochloride XR 2 weeks before the hospitalization, then stopped since inpatient psychiatrist prescribed sertraline. The subject continued to have suicidal thoughts without a plan. Per video visit with primary MD on 15Mar2021: The subject was stable with no suicidal ideation. Based on the last visit with the primary MD, suicidal ideation was no longer ongoing. Relevant tests were none. The action taken in response to the event for the blinded vaccine therapy was not applicable. The clinical outcome of the event was recovered on 15Mar2021.

The investigator considered there was not a reasonable possibility that the event suicidal ideation was related to blinded vaccine therapy, concomitant drug, or clinical trial procedure.

Follow-up (03Mar2021 and 04Mar2021): New information reported includes: updated causality assessment (unrelated to concomitant drug), medical history (deficit hyperactivity disorder updated), clinical course (treatment details, released date).

Follow-up (21Apr2021): New information reported includes: reaction data (updated outcome), added medical history, concomitant drug details (stop date), additional clinical course (confirmed there was no documentation of knee pain, video visit with psychiatry MD and primary MD).

Case Comment: The company reasonably does not attribute the case to blinded study vaccine, (BNT162:PLACEBO), concomitant drugs or clinical trial procedure based on the pathophysiology of the event and the 1 month 7 days latency. Event suicidal ideation is more likely associated with the subject underlying psychological conditions.

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
18-DEC-2020 to 18-DEC-2020	Historical Vaccine	BNT162:PLACEBO (BLINDED THERAPY); Drug Indication: COVID-19 immunization (COVID-19 immunisation) Dose 1, on 18Dec2020 at 16:30 via intramuscular route at left deltoid, single dose
01-JAN-2015 to Ongoing	Relevant Med History	Attention deficit hyperactivity disorder (Attention deficit hyperactivity disorder);
31-AUG-2020 to Ongoing	Relevant Med History	Anxiety (Anxiety);
Unknown	Past Drug Event	CONCERTA (CONCERTA); Drug Indication: Attention deficit

ADDITIONAL INFORMATION**23. OTHER RELEVANT HISTORY continued**

From/To Dates	Type of History / Notes	Description
		hyperactivity disorder (Attention deficit hyperactivity disorder), Drug Reaction: Anger (Anger) at 36mg orally TR24 SR Tab 1 tab daily; experiencing side effects of anger, agitation and appetite reduction
Unknown	Past Drug Event	CONCERTA (CONCERTA); Drug Indication: Attention deficit hyperactivity disorder (Attention deficit hyperactivity disorder), Drug Reaction: Agitation (Agitation) at 36mg orally TR24 SR Tab 1 tab daily; experiencing side effects of anger, agitation and appetite reduction
Unknown	Past Drug Event	CONCERTA (CONCERTA); Drug Indication: Attention deficit hyperactivity disorder (Attention deficit hyperactivity disorder), Drug Reaction: Appetite decreased NOS (Decreased appetite) at 36mg orally TR24 SR Tab 1 tab daily; experiencing side effects of anger, agitation and appetite reduction
08-DEC-2020 to Ongoing	Relevant Med History	Depression (Depression);

25b. Name And Address of Reporters continued
Nicola Klein MD, PhD

UNITED STATES

(b) (6)

UNITED STATES

Ludy Lemus
1 Kaiser Plaza 16B/1650 Response Road
Oakland/Sacramento, CA 94612/95815
UNITED STATES

David Cooper

UNITED STATES

Christine Cash
1 Kaiser Plaza 16B
Oakland, CA 94612
UNITED STATES

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SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last) PRIVACY	1a. COUNTRY UNITED STATES	2. DATE OF BIRTH Day Month Year (b) (6) 2005	2a. AGE 15 Years	3. SEX Male	3a. WEIGHT 65.50 kg	4-6 REACTION ONSET Day Month Year 26 JAN 2021	8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION <input type="checkbox"/> PATIENT DIED <input checked="" type="checkbox"/> INVOLVED OR PROLONGED INPATIENT HOSPITALISATION <input type="checkbox"/> INVOLVED PERSISTENT OR SIGNIFICANT DISABILITY OR INCAPACITY <input type="checkbox"/> LIFE THREATENING
7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data) Event Verbatim [PREFERRED TERM] (Related symptoms if any separated by commas) Depression exacerbation [Depression] Case Description: A PHASE 1/2/3, PLACEBO-CONTROLLED, RANDOMIZED, OBSERVER-BLIND, DOSE-FINDING STUDY TO EVALUATE THE SAFETY, TOLERABILITY, IMMUNOGENICITY, AND EFFICACY OF SARS-COV-2 RNA VACCINE CANDIDATES AGAINST COVID-19 IN HEALTHY INDIVIDUALS This is a report from an interventional study source for Protocol C4591001 sponsored by BioNTech, managed and reported by Pfizer on the sponsor's (Continued on Additional Information Page)							

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name) #1) BNT162;PLACEBO (Code not broken)	20. DID REACTION ABATE AFTER STOPPING DRUG? <input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> NA
15. DAILY DOSE(S) Blinded, Information withheld.	16. ROUTE(S) OF ADMINISTRATION Blinded, Information withheld.
17. INDICATION(S) FOR USE #1) COVID-19 immunization (COVID-19 immunisation)	21. DID REACTION REAPPEAR AFTER REINTRODUCTION? <input type="checkbox"/> YES <input type="checkbox"/> NO <input checked="" type="checkbox"/> NA
18. THERAPY DATES(from/to) #1) 11-JAN-2021 12:50:00 / 11-JAN-2021 12:50:00	19. THERAPY DURATION #1) Unknown

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction) #1) LEXAPRO (ESCITALOPRAM OXALATE) ; DEC-2020 / 15-JAN-2021 #2) PROPRANOLOL (PROPRANOLOL) ; SEP-2020 / Ongoing #3) VITAMIN D [VITAMIN D NOS] (VITAMIN D [VITAMIN D NOS]) (Continued on Additional Information Page)	
23. OTHER RELEVANT HISTORY. (e.g. diagnostics, allergies, pregnancy with last month of period, etc.) From/To Dates 2012 to Ongoing 2016 to Ongoing	Type of History / Notes Relevant Med History Relevant Med History Description Eyeglasses wearer (Corrective lens user) Allergic rhinitis (Rhinitis allergic)

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER Pfizer Inc Head Drug Safety Surveillance 219 East 42nd Street New York, New York 10017 UNITED STATES Phone: 212 733 5544	26. REMARKS
24b. MFR CONTROL NO. 2021241177	25b. NAME AND ADDRESS OF REPORTER Gretchen Crook
24c. DATE RECEIVED BY MANUFACTURER 08-MAR-2021	25a. REPORT TYPE <input type="checkbox"/> INITIAL <input type="checkbox"/> FOLLOWUP:
24d. REPORT SOURCE <input checked="" type="checkbox"/> STUDY <input type="checkbox"/> LITERATURE <input checked="" type="checkbox"/> HEALTH PROFESSIONAL <input type="checkbox"/> OTHER:	UNITED STATES (b) (6) (Continued on Additional Information Page)
DATE OF THIS REPORT 02-MAY-2021	

ADDITIONAL INFORMATION**7+13. DESCRIBE REACTION(S) continued**

behalf.

A 15-year-old male subject received first dose of blinded study vaccine (BNT162;PLACEBO) on 11Jan2021 at 12:50 and second dose on 01Feb2021 at 08:31, both via intramuscular (IM) route at left deltoid at single dose for COVID-19 immunization. Ongoing medical history included eye glasses from 2012, allergic rhinitis from 2016, depression from 2018, anxiety from 2018, and attention deficit hyperactivity disorder from 2018. Other medical history included asthma from 2006 to 2018. Concomitant medications included escitalopram oxalate (LEXAPRO) for anxiety/depression from Dec2020 to 15Jan2021, ongoing propranolol for anxiety from Sep2020, and vitamin D NOS (VITAMIN D) as supplements from Sep2020 and ongoing. The subject had no concomitant vaccines on same date of the investigational vaccines or prior vaccines (within 4 weeks). The subject experienced depression exacerbation on 26Jan2021, which required a visit to emergency room (ER) and resulted in hospitalization for 5 days. The clinical course was following: the subject had history of depression and anxiety. The subject expressed suicidal thoughts to parents on 26Jan2021 and his parents took subject to ER. The subject expressed continued suicidal ideation in ER so inpatient treatment was arranged. The subject had change in medications and counseling in the hospital. The escitalopram oxalate was stopped. The subject received fluvoxamine from 26Jan2021 at 100mg, and risperidone (RISPERDAL) from 29Jan2021 at 1 mg, both ongoing for anxiety/depression. The subject also received ongoing folic acid from 02Mar2021 for anxiety/depression. Propranolol and vitamin D remained unchanged. No diagnostic studies on lab tests reported by the subject. The action taken in response to the event for blinded study vaccine was not applicable (reported as dose not changed by the investigator). The outcome of the event was recovered on 30Jan2021. The subject was discharged on 30Jan2021 with continued outpatient follow-up.

The investigator considered there was not a reasonable possibility that the event depression exacerbation was related to blinded study vaccine (BNT162;PLACEBO), concomitant drugs or clinical trial procedure.

Follow-up (08Mar2021): New information reported includes: medication details (start date of risperidone and propranolol).

Case Comment: Based on the information currently provided, the company considers there is not a reasonable possibility that the event depression exacerbation is related to the blinded study vaccine, concomitant medication or clinical trial procedure. The young patient having ongoing depression, anxiety and attention deficit hyperactivity disorder prior to the vaccine use, the event depression exacerbation is more likely due to worsening of the subject underlying psychiatric disorders

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION continued

#3) VITAMIN D [VITAMIN D NOS] (VITAMIN D [VITAMIN D NOS]) ; SEP-2020 / Ongoing

23. OTHER RELEVANT HISTORY continued

From/To Dates	Type of History / Notes	Description
2006 to 2018	Relevant Med History	Asthma (Asthma);
2018 to Ongoing	Relevant Med History	Depression (Depression);
2018 to Ongoing	Relevant Med History	Anxiety (Anxiety);
2018 to Ongoing	Relevant Med History	Attention deficit hyperactivity disorder (Attention deficit hyperactivity disorder);

25b. Name And Address of Reporters continued
Gretchen Crook

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(b) (6)

ADDITIONAL INFORMATION

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