

From: Caubel, Patrick
Sent: Wed, 16 Dec 2020 20:54:58 +0000
To: Cohn, Amanda (CDC/DDID/NCIRD/OD)
Subject: RE: Pfizer/BNT safety reporting
Attachments: Initial_Redacted 2020497114 pdf (002).pdf, US case.pptx

Hi Amanda,

(b)(4)

Thanks
Patrick

From: Cohn, Amanda (CDC/DDID/NCIRD/OD) <anc0@cdc.gov>
Sent: Wednesday, December 16, 2020 3:15 PM
To: Caubel, Patrick <Patrick.Caubel@pfizer.com>
Subject: [EXTERNAL] RE: Pfizer/BNT safety reporting

Hi Patrick,

Absolutely agree and our intention was to make sure Pfizer had been alerted. I'll give you a call in a bit to think through the best way to make this happen. We were still information gathering when the report came out, so we don't want to raise everything to your attention but clearly this was a miss. I'd like to also ask FDA to make sure we don't overstep.

Thanks,
Amanda

From: Caubel, Patrick <Patrick.Caubel@pfizer.com>
Sent: Wednesday, December 16, 2020 1:22 PM
To: Cohn, Amanda (CDC/DDID/NCIRD/OD) <anc0@cdc.gov>
Subject: Pfizer/BNT safety reporting

Dear Dr Cohn,

(b)(4)

Thanks in advance for considering my proposal.
Kind regards,
Patrick

Patrick Caubel, MD
Head WW Safety Pfizer
215-272-4376

Field Name	Field Value
country	US
language	en
report about covid vaccine	Yes
reporting type	AE
reporter_type	Healthcare Professional reporting for a patient
patient name	[REDACTED]
dob	[REDACTED]
age group	Adult (18-64 Years)
current age	32
current age unit	Years
gender	Female
is pregnant	No
race	[REDACTED]
ethnicity	[REDACTED]
medical qualification reporter	(b)(6)
allowed to contact	Yes
reporter name	[REDACTED]
address street	[REDACTED]
city	[REDACTED]
state	[REDACTED]
zipcode	[REDACTED]
reporter country	US
phone	[REDACTED]
email	[REDACTED]
allowed to contact hcp	Yes
hcp fullname	[REDACTED]
hcp address street	[REDACTED]
hcp city	[REDACTED]
[REDACTED]	[REDACTED]
hcp zipcode	[REDACTED]
hcp phone	[REDACTED]
covid_vaccine_details	[[product=COVID 19, brand=Pfizer, lot_number=EK5730, administration_date=15/12/2020, administration_time=05:45 PM, administrator_route=Intramuscular, vaccine_location=Right arm, dose_number=1]]
facility type vaccine	Hospital
facility name	[REDACTED]
facility address street	[REDACTED]
facility city	[REDACTED]
facility state	[REDACTED]
facility zipcode	[REDACTED]
facility country	US
facility phone	[REDACTED]
if other vaccine in fourweeks	No

other medications in twoweeks	Nuvaring
adverse_event	10 min after injection, she reported feeling dizzy and couldnt catch breath, so she stood up. Then felt dizzy. Was breathing fast, deep but no wheezing. No chest tightness, no
adverse event start date	15/12/2020
adverse event start time	06:00 PM
adverse event country	US
ae_resulted_in	[Emergency room/department or urgent care]
if_patient_recovered	Recovered
if_treatment_ae	Yes
ae_treatment	benedryll 25 mg po @ 6pm. 1:1000 0.3 ml IM epi
if_covid_prior_vaccination	No
if_covid_tested_post_vaccination	No
known_allergies	no
other_medical_history	none
explicit_consent	Yes
requestId	ae67c08c-bda4-4766-803e-30f9bb4d3d5f
submittedTime	2020-12-15T22:59:48.500208-05:00
referenceId	3XLjH-tCwj3-Vm8cB
prd	15-Dec-2020 (22:59:48)

Dyspnea, dizziness, respiration abnormal

US case - as of 16 Dec 2020

AER# (b)(6)

- report from the COVID19 self-reporting tool

32-year-old woman, (b)(6) for a patient No Allergies to medications, food, or other products Administration date=12/15/2020 administration time=05:45 PM, IM Right arm, dose 1 No previous vaccine w/in 4 weeks Meds: Nuvaring AE reported @12/15/2020 6 PM : 10 min after injection, "she reported feeling dizzy and couldn't catch breath, so she stood up. Then felt dizzy. Was breathing fast, deep but no wheezing. No chest tightness, no" benedryll 25 mg po @ 6pm. 1:1000 0.3 ml IM epi Treated in Emergency room/department or urgent care Recovered, no covid test, no prior covid infection B/L EK5730