Medical Summary

Case Number: **2021101980**

General Case Information

Report Type	Pfizer Spons Interv Study
Initial Receipt Date	01-Feb-2021
Case Creation Time	02-Feb-2021 06:00
Country of Incidence	UNITED STATES
Health Care Professional	Yes

Study Information

Study Project ID	PF-07302048
Study ID	C4591001
Study Center ID	1007
Pat. ID	10071620

Patient Information

Age	12 Years
Date of Birth	22-MAY-2008
Weight	57.100 kg
Patient Height in.	155.500 cm
Race Information	Caucasian
Gender	Female
Pregnant	

Reporter Information

Reporter Type	Physician	**Country**	UNITED STATES	**Email Address**	IN CONFIDENCE
Reporter Name	Dr. Robert Frenck				

Narrative / Comment

Narrative

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 behalf.

A 12-year-old female subject received blinded study vaccine (BNT162; PLACEBO), first dose on 30Dec2020 at 10:26 and second dose on 20Jan2021 at 16:30, both intramuscularly on left deltoid at single doses for coronavirus disease 2019 (COVID-19) immunization. Ongoing medical history included attention deficit disorder and anxiety, both from 2018. Ongoing concomitant medications included lisdexamfetamine mesilate (VYVANSE) for attention deficit hyperactivity disorder (ADHD) from 2018, paracetamol (TYLENOL) and ibuprofen both for fever and pain from 20Jan2021 and ketorolac tromethamine (TORADOL) for pain from 23Jan2021. The subject had no concomitant vaccines administered on same date of the investigational vaccine or prior vaccines within 4 weeks. The subject experienced generalized functional neurological disorder on 21Jan2021 which required a visit to emergency room and resulted in hospitalization. Clinical course was reported as follows: subject was with history only significant for well-controlled ADHD. The subject did not have any history of abdominal pain/complaints. She received the second vaccine on 20Jan2021. Her reactogenicity symptoms included fever to 101.4 degrees Fahrenheit (F) on day 2 with severe chills, myalgia, arthralgia, fatigue and headache. Her fever resolved. She remained with moderate to severe fatigue, headache, chills, myalgia and arthralgia which were present on day 7. She also developed mild diarrhea on day 7. She presented to the emergency department on 21Jan2021 with severe abdominal and flank pain, myalgia and headache. COVID-19 polymerase chain reaction (PCR)/ COVID-19 nucleic acid amplification test (NAAT) was negative (manufactured by COPAN and distributed by CLIA certified lab). She was well-appearing, well-hydrated, with stable vital signs. Abdominal ultrasound (ultrasound right lower quadrant (RLQ)) done on 21Jan2021 to rule out (r/o) appendicitis. Appendix not visualized, but there were no secondary signs; no ultrasound findings to support diagnosis of appendicitis. Her urinalysis showed moderate blood without red blood cells (RBC) so she was screened for rhabdomyolysis,

which was negative. Urine culture was negative. She improved with intravenous fluids and paracetamol/ibuprofen and was discharged home. She returned to the emergency department on 23Jan2021 with continued severe abdominal pain and headache; also with lower back, neck pan and chest pain. Computerized tomogram (CT) abdomen/pelvis was normal, noncontrast CT of the abdomen and pelvis; no urinary tract calculi. Ultrasound RLQ with pelvis/doppler was normal pelvic ultrasound. Electrocardiogram (ECG) did not demonstrate significant cardiac pathology. She improved with intravenous fluids and ketorolac tromethamine. Subject was discharged to home. After 1 to 2 days, the pain progressively returned. The subject again returned to the emergency department on 30Jan2021 with worsening fatigue, abdominal pain (generalized), tenderness to touch of her neck, back, chest and bilateral legs. Her vital signs were stable. Physical examination (PE) significant for pain to light-moderate palpation over lower back, bilateral buttocks, posterior neck and bilateral scapular regions. Her neurological exam was normal. Complete blood count (CBC) with hemoglobin (Hgb) 14.1 g/dL (normal: 12.0 to 16.0), hematocrit (Hct) 41.3 % (normal: 36.0 to 46.0), platelets 471 x10 3/mm3 (normal: 135 to 466), sedimentation rate 9, lipase 39.0 iu/L (normal: 12.0 to 50.0), blood urea nitrogen (BUN) 25 mg/dL (normal 8.0 to 18.0), BUN 13, creatinine 0.43 mg/dl (range 0.42-0.71), alanine aminotransferase (ALT) 22, aspartate aminotransferase (AST) 21, total bilirubin 0.2, and C-reactive protein (CRP) less than 0.40 mg/dL (normal: less than or equal to 0.40), white blood cell count (WBC) 8.82 x10 3/mm3 (normal: 4.5 to 13.5) and creatine phosphokinase (CPK) 123 iu/L (normal: 31 to 145). Urinalysis (UA) was normal without blood. Although stable, the subject was hospitalized for observation. During admission, her exam, test results and imaging were reassuring against neurologic or anatomical causes for pain. The focus of admission was pain control and a developing psychiatric network to provide support. The pain team was consulted who prescribed gabapentin with uptitration over the following weeks (200 mg daily orally for 1 week, then increase to 200 mg twice daily (BID) orally for 1 week then increase to 200 mg twice daily (TID) orally). She was also prescribed naproxen 375 mg BID for 5 days (followed by as needed (PRN)), paracetamol every 6 hours while awake and methocarbamol (ROBAXIN) 750 mg PRN. She was referred to psychology and physical therapy. Her symptoms were gradually improving. The subject also endorsed constipation during her admission. She was prescribed macrogol 3350 (MIRALAX) 1 capsule (cap) BID. She also started on famotidine 20 mg BID due to symptoms of gastritis secondary to prolonged ibuprofen use. It was also noted that the subject was seen as an outpatient by her primary care provider on 24Jan2021 for a very small boil (erythema measuring less than 0.25 cm with small white tip in the center) on her left inferior labia majora. She was prescribed topical clindamycin 1% gel for 7 days and warm compress. The boil drained at home and resolved on 26Jan2021. The assessment of the cause for the vulvar boil was done per site investigator; upon further discussion, the etiology of methicillin-resistant staphylococcus aureus (MRSA) had been revised to probable staph infection. The boil drained at home after warm compresses without incision and drainage by a medical provider. Therefore, no culture was done. The subject had no known history of MRSA exposure or prior risk factor for MRSA. This was not thought to be the cause of her fever or abdominal pain. The subject had not onset of menses so the conditions were not related. Abdominal examination findings at each of the three emergency room (ER) visits as below: On 21Jan2021, emergency department (ED) abdominal physical examination (PE) findings: Soft, tender to palpation over bilateral lower quadrants, bilateral costovertebral angle (CVA), no rebound or guarding, +BS, no hepatosplenomegaly. On 23Jan2021, ED abdominal PE findings: Soft, non-distended, pain and guarding in the Image result for right lower quadrant (RLQ), no rebound or guarding, +BS, no hepatosplenomegaly. On 30Jan2021, ED abdominal PE findings: NABS. Guarding present initially, but then tolerates exam. TIP across all quadrants. ND with no organomegaly. The subject's diagnose updated to generalized functional neurologic disorder on 09Apr2021 and functional abdominal pain. It was reported that subject had functional abdominal pain from 28Feb2021, constipation from 28Feb2021, and gastritis from 30Jan2021, all ongoing. On 24Mar2021, the subject had worsening of event. The subject had multiple life stressors in the months preceding her diagnosis of functional neurologic disorder. Since that time, the subject continued with diffuse myalgia, dizziness, headaches, decreasing strength in her lower extremities, abdominal pain, vomiting, poor appetite, constipation, and intermittent rash on upper extremities. In addition, the subject had "passed out twice" between 19Feb2021 and 20Feb2021. Her work-up included psychology, medical pain consult, gastrointestinal (GI) consult for abdominal pain and poor oral intake status post (S/p) esophagogastroduodenoscopy (EGD) with normal biopsies, neurology consult with normal MRI spine, initiation of escitalopram oxalate for anxiety. Since her hospital discharge on 13Mar2021, the subject continued with lower extremity weakness and numbness progressing to inability to walk, emesis and regurgitation of most oral (PO), word finding difficulties, moodiness, longer "spells" consisting of falling down/over, both arms shaking, eyes rolling back and unresponsiveness lasting up to 6 minutes, as well as more frequent "zoning out" episodes. The subject weight had decreased from 57. 1 kg on 06Mar2021 to 52.6 kg on 09Apr2021. The subject presented to the emergency department on 09Apr2021 due to the worsening symptoms above. The subject was well-appearing and interactive with stable vital signs. Neurological exam consistent with functional signs. Reflexes were normal. The subject was confined to a wheelchair with reports of lower extremity paralysis but was able to lift her leg onto the wheelchair at one point. Her abdomen was soft, nontender without masses or organomegaly. The subject labs were significant for glucose of 47 (asymptomatic). The subject received D25 intravenous bolus with resolution

of hypoglycemia. The subject was admitted for observation and management of symptoms. The "spells" observed in the hospital were less likely consistent with seizure given distractibility, variability of episodes, and lack of postictal phase. It was reported that her neurologic examination was consistent with a functional neurological disorder. The subject was evaluated by speech therapy who recommended Videofluoroscopic Swallow Study/ fiberoptic endoscopic evaluation of swallowing (VSS/FEES) for further evaluation of oral-motor dysfunction. VSS showed functional oral motors skills and adequate airway protection but severe gagging and emesis with all PO. The UES appeared to be functioning on VSS. The subject did not initiate swallowing. The subject was evaluated by physical therapist/occupational therapist (PT/OT) who recommended an inpatient rehabilitation stay, However, a direct inpatient admit was not possible. The subject was discharged to home on 14Apr2021 with the plan for outpatient rehabilitation to include OT/PT/Speech therapy, as well as psychotherapy. The subject was discharged from the hospital on 14Apr2021; however, she was then transferred to the inpatient pediatric rehabilitation unit where she remained. Her rehabilitation had included physical therapy, occupational therapy, speech therapy, therapeutic recreation, and psychosocial services. Subject remained with moderate pain requiring paracetamol, ibuprofen, and cyclobenzaprine hydrochloride (FLEXERIL) as previously prescribed. She had made progress in her ability to walk. She continued with gagging and was requiring nasogastric tube feedings, but she was eating small amounts of soft foods. She was receiving psychotherapy and remained on escitalopram oxalate (LEXAPRO). Relevant laboratory information included: Liver function test (LFT) was last drawn on 30Jan2021 which showed within normal limits (WNL). However, the subject did not have LFT's drawn during this admission. Furthermore, the subject has not had toxicology or ceruloplasmin screening. Other laboratory tests on 09Apr2021 included: sodium which showed 135 mmol/L (normal range: 136-145), potassium 3.4 mmol/L (normal range 3.3- 4.7), chloride 102 mmol/L (normal range: 100-112), Carbon dioxide (CO2) 16 mg/dl (normal range: 17 to 31), BUN 6 mg/dl (normal range: 8 to 18), creatinine 0.43mg/dl (normal range: 0.42 to 0.71), glucose 47 mg/dl (normal range: 65 to 106) and rapid glucose 213 mg/dl (normal range: 65 to 106) following D25. COVID testing was not performed. The subject remained in inpatient rehabilitation until 01Jun2021. She continued to demonstrate functional weakness and abnormal movements of her legs with slow improvement. She was able to progress and use her legs for more functional activities such as walking with a walker. She was not able to progress to walking without assistive device. She had one episode of functional episode of shaking her bilateral upper extremities and right upper extremity during her rehabilitation which resolved within 24 hours. She continued with anxiety which was being treated with escitalopram oxalate from 13Mar2021 and ongoing and alprazolam (ATARAX) from Feb2021 and ongoing. Her generalized pain was slowly improving on cyclobenzaprine hydrochloride. She was voiding independently during her rehabilitation stay but did require occasional urinary catherization for elevated bladder volumes. This was believed to be functional withholding. She continued with constipation treated with macrogol 3350 from 28Feb2021 and ongoing and senna (SENOKOT) from 27May2021 and ongoing. She was requiring nasogastric tube feedings for nutrition. She had very limited oral intake. Her swallow study and speech evaluation were consistent with oral aversion. Due to insurance issues, subject was discharged from inpatient rehabilitation on 01Jun201 and transferred to an inpatient psychiatric facility. The parents decided to take subject out of the psychiatric facility against medical advice. She was discharged to home on 01Jun2021. It was reported that subject had the following medications: bisacodyl suppository for constipation from 27Apr2021, paracetamol from 21Jan2021 for generalized functional neurologic pain, paracetamol from 21Jan2021 and cyclobenzaprine hydrochloride from 25Feb2021, both for generalized functional neurologic pain, ibuprofen from 19Mar2021 for functional generalized neurologic pain, and lansoprazole (PREVACID) from 14Mar2021 for functional abdominal pain, all ongoing, famotidine (PEPCID) from 30Jan2021 to Apr2021 for gastritis and pregabalin (LYRICA) from 25Feb2021 to 28Mar2021 for generalized functional neurologic pain. The action taken in response to the event for blinded study vaccine was not applicable. Outcome of the event was not recovered.

The investigator considered there was not a reasonable possibility that the event generalized functional neurological disorder was related to blinded study vaccine, concomitant drugs or clinical trial procedure. The PI did not feel that the subject's symptology was consistent with a vaccine related adverse event.

Follow-up (10Feb2021): New information reported includes: lab data (abdominal PE), event data (SAE updated form functional neurologic pain to generalized functional neurologic pain, onset date) and clinical course (no history of abdominal pain).

Follow-up (02Apr2021): New reported information includes: reporter information.

Follow-up (20Apr2021): New information reported includes: SAE term updated from generalized functional neurologic pain to generalized functional neurological disorder.

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Follow-up (17May2021): New information reported includes: medical history.

Follow-up (08Jun2021): This is a follow-up report combining information from duplicate reports 2021101980 and 2021418472. The current and all subsequent follow-up information will be reported under manufacturer report number 2021101980. New information reported includes: lab data, reaction data (treatment), outcome (updated to not recovered) and clinical course (worsening of event, hospitalization information and subject status).

Case Comment

Based on the information available and on the pathophysiology of the event company does not reasonably attribute the reported event as related to study vaccine, concomitant drugs, or clinical trial procedure. The event was likely due to subject underlying contributory factors

PSUR/Line Listing Comment

This case is cross-referenced to case 2021291329: same patient, same study, different event.

Case Serious	Listedness Determination	Case Causality	Case Outcome
Yes	Unlisted	No	Not recovered/Not resolved

Medications - Suspect

#	Product Name Generic Name	Reported Indication	Duration of Administration	Total Dosage Total Dose to Primary Event / Units	Product Event Delay Product Event Latency	Action Taken	Dechallenge Results Rechallenge Results
1	BNT162;PLACEBO BNT162;PLACEBO	COVID-19 immunization(COVID-19 immunisation)		Blinded Blinded	7 hrs 30 min 7 hrs 30 min	Not Applicable	N/A N/A

Dosage Regimens

#	Start Date/Time	Stop Date/Time	Dose	Frequency	Patient Route of Administration
1	20-JAN-2021 16:30:00	20-JAN-2021 16:30:00	Blinded	Blinded	Blinded

Medications - Concomitant

#	Product Name	Generic Name	Reported Indication	Duration of Administration
1	TYLENOL	PARACETAMOL	fever(Pyrexia) pain(Pain)	

Dosage Regimens

#	Dose
1	

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#	Product Name	Generic Name	Reported Indication	Duration of Administration
2	IBUPROFEN	IBUPROFEN	fever(Pyrexia) pain(Pain)	
	Dosage Regimens **#** **Dose** 1			
3	TORADOL	KETOROLAC TROMETHAMINE	Pain(Pain)	
	Dosage Regimens **#** **Dose** 1			
4	VYVANSE	LISDEXAMFETAMINE MESILATE	ADHD(Attention deficit hyperactivity disorder)	
	Dosage Regimens **#** **Dose** 1			

Devices

No information present

Events

#	Description as Reported	Preferred Term Lower Level Term	Onset Date/Time Stop Date/Time	Duration	Onset Latency Onset From Last Dose		Seriousness Criteria	Outcome of Event
1	generalized functional neurological disorder	Conversion disorder Functional neurological symptom disorder	21-JAN-2021		7 hrs 30 min 7 hrs 30 min		Yes Hospitalized	Not recovered/Not resolved

Event Assessment

No information present

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Hospitalization Information

Description as Reported	Hospitalization Start Date	Hospitalization End Date	Duration of Hospitalization	Event Caused Hospitalization	Hospitalization Prolonged	Hospital Discharge Summary Available
generalized functional neurological disorder		14-APR-2021		Yes	No	No

Patient Relevant History

#	Start	Stop Date	Ongoing	Condition Type	Coded PT
1	30-DEC-2020	30-DEC-2020		Historical Vaccine	BNT162;PLACEBO (BLINDED THERAPY)(Drug Indication: COVID-19 immunisation)
	Notes: Dose 1 at 10:26, IM in the left deltoid at single dose				
2	2018		Yes	Relevant Med History	attention deficit disorder (Attention deficit hyperactivity disorder)
	Notes: well-controlled				
3	2018		Yes	Relevant Med History	anxiety (Anxiety)

Patient Lab Tests

#	Date	Test Name	Results	Norm High	Norm Low	Assessment
1	30-JAN-2021	Alanine aminotransferase	22			
2	30-JAN-2021	Aspartate aminotransferase	21			
3		Barium swallow	functional oral motors skills and adequate airway			
4		Biopsy	normal			
5	30-JAN-2021	Blood bilirubin	0.2			
6	09-APR-2021	Blood chloride	102 mmol/L	112	100	
7	30-JAN-2021	Blood creatine phosphokinase	123 IU/l	145	31	
8	30-JAN-2021	Blood creatinine	0.43 mg/dl	0.71	0.42	
9	09-APR-2021	Blood creatinine	0.43 mg/dl	0.71	0.42	
10	09-APR-2021	Blood glucose	47 mg/dl	106	65	
11	09-APR-2021	Blood glucose	213 mg/dl	106	65	
12	09-APR-2021	Blood potassium	3.4 mmol/L	4.7	3.3	

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#	Date	Test Name	Results	Norm High	Norm Low	Assessment
13	09-APR-2021	Blood sodium	135 mmol/L	145	136	
14	30-JAN-2021	Blood urea	25 mg/dl	18.0	8.0	
15	30-JAN-2021	Blood urea	13 mg/dl	18.0	8.0	
16	09-APR-2021	Blood urea	6 mg/dl	18.0	8.0	
17		Body temperature	101.4 Fahrenheit			
18	09-APR-2021	Carbon dioxide	16 mmol/L	31	17	
19	23-JAN-2021	Computerised tomogram abdomen	normal noncontrast CT of the abdomen and pelvis.			
20	23-JAN-2021	Computerised tomogram pelvis	normal noncontrast CT of the abdomen and pelvis.			
21	30-JAN-2021	C-reactive protein	0.40 mg/dl			
22	21-JAN-2021	Culture urine	negative			Negative
23	23-JAN-2021	Electrocardiogram	did not demonstrate significant cardiac pathology			
24	30-JAN-2021	Haematocrit	41.3 %	46.0	36.0	
25	30-JAN-2021	Haemoglobin	14.1 g/dl	16.0	12.0	
26	21-JAN-2021	Investigation	negative			Negative
27	30-JAN-2021	Lipase	39.0 IU/l	50.0	12.0	
28	30-JAN-2021	Liver function test	within normal limits (WNL)			
29		Magnetic resonance imaging spinal	normal			
30	30-JAN-2021	Neurological examination	normal			
31	09-APR-2021	Neurological examination	consistent with functional signs			
32	21-JAN-2021	Physical examination	Soft, tender to palpation over bilateral lower			
33	23-JAN-2021	Physical examination	Soft, non-distended, pain and guarding in the RLQ,			
34	30-JAN-2021	Physical examination	NABS. Guarding present initially, but then			
35	30-JAN-2021	Physical examination	significant for pain to light-moderate palpation			
36	30-JAN-2021	Platelet count	471 x10 3/mm3	466	135	
37	30-JAN-2021	Red blood cell sedimentation	9			

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		rate				
#	Date	Test Name	Results	Norm High	Norm Low	Assessment
38	21-JAN-2021	SARS-CoV-2 test	negative			Negative
39	23-JAN-2021	Ultrasound Doppler	normal pelvic ultrasound			
40	21-JAN-2021	Ultrasound scan	appendix not visualized; no ultrasound findings to			
41	21-JAN-2021	Urine analysis	moderate blood without RBC			
42	30-JAN-2021	Urine analysis	normal without blood			
43	21-JAN-2021	Vital signs measurement	stable			
44	30-JAN-2021	Vital signs measurement	stable			
45	09-APR-2021	Weight	52.6 kg			
46	30-JAN-2021	White blood cell count	8.82 x10 3/mm3	13.5	4.5	

Relevant Tests

From: Steve Kirsch [stk@m10.io]
Sent: 6/25/2021 11:22:50 AM
To: Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]
Subject: Re: [EXTERNAL] this is the girl in the pfizer clinical trial

Great. Thank you.

Sent from my iPhone

On Jun 25, 2021, at 7:55 AM, Woodcock, Janet <Janet.Woodcock@fda.hhs.gov> wrote:

I forwarded the last email you sent to the team and of course FDA evaluates every serious adverse event related to a clinical trial, and intensively if in a healthy population. Janet Woodcock

---

From: Steve Kirsch <stk@m10.io>
Sent: Friday, June 25, 2021 9:21 AM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: [EXTERNAL] this is the girl in the pfizer clinical trial

Janet: Why isn't the FDA investigating this???

From: Patrick deGaray <pdegaray@gmail.com>
Sent: Friday, June 25, 2021 5:43 AM
To: Steve Kirsch <stk@m10.io>
Cc: Stephanie de Garay <Shdegaray@outlook.com>
Subject: Re: info needed

Steve,

Been a little crazy here since Maddie's last MRI, she's struggling to hold her head up and can't stand on her own. Stephanie will resend the folder today.

Patrick

From: Woodcock, Janet [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7B0453354A9A427DB0A66A86C7A36F3D-JANET.WOODC]
Sent: 6/30/2021 3:46:25 PM
To: Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]
Subject: RE: [EXTERNAL] Maddie de Garay (12 years old) victim of the Pfizer trial

Thanks. jw

-----Original Message-----
From: Marks, Peter <Peter.Marks@fda.hhs.gov>
Sent: Wednesday, June 30, 2021 1:55 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Cc: Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Subject: FW: [EXTERNAL] Maddie de Garay (12 years old) victim of the Pfizer trial

Dear Janet,

FYI.

Best Regards,
Peter

-----Original Message-----
From: Fink, Doran <Doran.Fink@fda.hhs.gov>
Sent: Wednesday, June 30, 2021 1:38 PM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>
Cc: Gruber, Marion <Marion.Gruber@fda.hhs.gov>
Subject: FW: [EXTERNAL] Maddie de Garay (12 years old) victim of the Pfizer trial

Dear Peter,

Pfizer has provided the attached updated narrative on this study participant, which provides a more detailed account of her illness and diagnosis of a functional neurologic disorder based on extensive specialist evaluation and consistent exam, labs, and imaging. This illness is considered not due to an organic process, and while temporally associated with vaccination it is difficult to explain a physiologically causal association.

Thanks,
Doran

Doran L. Fink, MD, PhD
Deputy Director – Clinical
Division of Vaccines and Related Products Applications FDA/CBER, Office of Vaccines Research and Review
(301) 796-2640

-----Original Message-----
From: Gurtman, Alejandra C <Alejandra.Gurtman@pfizer.com>
Sent: Wednesday, June 30, 2021 10:30 AM
To: Fink, Doran <Doran.Fink@fda.hhs.gov>
Cc: Gruber, Marion <Marion.Gruber@fda.hhs.gov>; Boyce, Donna <Donna.Boyce@pfizer.com>
Subject: RE: [EXTERNAL] Maddie de Garay (12 years old) victim of the Pfizer trial

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

Dear Doran,
Attached please find the updated narrative for this participant. Please note that it has been downloaded from our system and an official CIOMS form will follow but we wanted you to have the information.
I have been in regular contact with the Principal Investigator as well and his assessment remains that the events described are not related to the vaccine Please let me know if you have any questions.
Best regards
Alejandra

-----Original Message-----
From: Gurtman, Alejandra C
Sent: Tuesday, June 29, 2021 11:11 AM
To: Fink, Doran <Doran.Fink@fda.hhs.gov>; Boyce, Donna <Donna.Boyce@pfizer.com>
Cc: Gruber, Marion <Marion.Gruber@fda.hhs.gov>
Subject: RE: [EXTERNAL] Maddie de Garay (12 years old) victim of the Pfizer trial

Dear Doran
We are putting together a comprehensive narrative of the case for your review.
Hope to have it ready for you within the next day or so Best regards, Alejandra

Alejandra Gurtman, MD
Vice President
Pfizer Vaccine Clinical Research and Development Tel 845-602-2842 Cel (b) (6) Fax 845 474 3219
Email: alejandra.gurtman@pfizer.com

-----Original Message-----
From: Fink, Doran <Doran.Fink@fda.hhs.gov>
Sent: Tuesday, June 29, 2021 10:57 AM
To: Boyce, Donna <Donna.Boyce@pfizer.com>
Cc: Gruber, Marion <Marion.Gruber@fda.hhs.gov>; Gurtman, Alejandra C <Alejandra.Gurtman@pfizer.com>
Subject: RE: [EXTERNAL] Maddie de Garay (12 years old) victim of the Pfizer trial

Dear Donna,

Thanks for the update. Just to be clear, the narrative provided with the EUA submission (attached) was pretty scant on details, and no additional details were available from Pfizer when we asked during the review. I appreciated that Pfizer may not have had access to any additional details at the time, so it will be very helpful to have the more detailed follow-up that is forthcoming.

Thanks,
Doran

Doran L. Fink, MD, PhD
Deputy Director - Clinical
Division of Vaccines and Related Products Applications FDA/CBER, Office of Vaccines Research and Review
(301) 796-2640

-----Original Message-----
From: Boyce, Donna <Donna.Boyce@pfizer.com>
Sent: Tuesday, June 29, 2021 9:49 AM
To: Fink, Doran <Doran.Fink@fda.hhs.gov>
Cc: Gruber, Marion <Marion.Gruber@fda.hhs.gov>; Gurtman, Alejandra C <Alejandra.Gurtman@pfizer.com>
Subject: RE: [EXTERNAL] Maddie de Garay (12 years old) victim of the Pfizer trial

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

Dear Doran,
My apologies. I thought this message had been sent to you last week. You are correct and this is participant 10071620. This case from the COVID-19 C4591001 study was reported in the EUA with a narrative. It was also presented to the ACIP working group and many other recommending bodies. We are collating the SAEs follow up and will send to you shortly. In the meantime, Dr Alejandra Gurtman spoke with Dr Frenck who is the Principal Investigator at Cincinnati's Children today and confirmed that this case is not related to the vaccine and that the participant has had extensive work up with consultations with various specialties including pulmonary, neurology, pain management and psychiatry with no findings of anything organic.
We will include all pertinent data in the follow up.
Best Regards,
Donna

-----Original Message-----
From: Fink, Doran <Doran.Fink@fda.hhs.gov>
Sent: Tuesday, June 29, 2021 9:32 AM
To: Boyce, Donna <Donna.Boyce@pfizer.com>
Cc: Gruber, Marion <Marion.Gruber@fda.hhs.gov>
Subject: RE: [EXTERNAL] Maddie de Garay (12 years old) victim of the Pfizer trial

Hi Donna,

Please update us on where things stand with this request so that we can get back to Peter Marks and Janet Woodcock.

Thanks,
Doran

Doran L. Fink, MD, PhD
Deputy Director - Clinical
Division of Vaccines and Related Products Applications FDA/CBER, Office of Vaccines Research and Review
(301) 796-2640

-----Original Message-----
From: Boyce, Donna <Donna.Boyce@pfizer.com>
Sent: Thursday, June 24, 2021 9:22 AM
To: Fink, Doran <Doran.Fink@fda.hhs.gov>
Cc: Gruber, Marion <Marion.Gruber@fda.hhs.gov>
Subject: RE: [EXTERNAL] Maddie de Garay (12 years old) victim of the Pfizer trial

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Doran,
Thanks for reaching out. I will look into this and get back to you as soon as possible.
Kind regards,
Donna

-----Original Message-----
From: Fink, Doran <Doran.Fink@fda.hhs.gov>
Sent: Thursday, June 24, 2021 8:23 AM
To: Boyce, Donna <Donna.Boyce@pfizer.com>
Cc: Gruber, Marion <Marion.Gruber@fda.hhs.gov>
Subject: FW: [EXTERNAL] Maddie de Garay (12 years old) victim of the Pfizer trial
Importance: High

Good morning Donna,

Janet Woodcock received the email below, and we are trying to gather more information so that she can respond quickly. Can Pfizer provide any information to clarify details of this purported adverse event (participant's name is in the email subject line)? We have reviewed again the information submitted with the adolescent EUA amendment, and the only SAE that could potentially fit the description is for the participant with Unique Subject ID: C4591001 1007 10071620, described as follows:

"The SAE of neuralgia was reported in 1 female participant 12 years of age who had 3 emergency room visits beginning 1 day after the second dose. She reported concurrent non-serious AEs of vulvar abscess, gastritis, and contact dermatitis. She subsequently had SAEs of abdominal pain and constipation. She had an extensive work-up including serial physical and laboratory examinations and was diagnosed with functional abdominal pain; she was referred to psychology and physical therapy, after which symptoms were reported as gradually improving."

Could Pfizer please also provide any available update on this participant?

Thanks,
Doran

Doran L. Fink, MD, PhD
Deputy Director - Clinical
Division of Vaccines and Related Products Applications FDA/CBER, Office of Vaccines Research and Review
(301) 796-2640

-----Original Message-----
From: Steve Kirsch <stk@m10.io>
Sent: Wednesday, June 23, 2021 11:41 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: [EXTERNAL] Maddie de Garay (12 years old) victim of the Pfizer trial

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do you know the story of this girl? She was in the Pfizer trial.

She is now permanently disabled. She has NO FEELING FROM WAIST DOWN. She has to be fed through a feeding tube.

Pfizer never reported this in their trial results.

How can you allow these trials to continue? Has anyone at FDA or CDC investigated?

-steve

From: Woodcock, Janet [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7B0453354A9A427DB0A66A86C7A36F3D-JANET.WOODC]
Sent: 6/25/2021 8:07:55 AM
To: Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]
Subject: RE: [EXTERNAL] Pfizer clinical trial did NOT report Maddie de Garay's result that she was paralyzed

Thx jw

-----Original Message-----
From: Marks, Peter <Peter.Marks@fda.hhs.gov>
Sent: Friday, June 25, 2021 8:08 AM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: RE: [EXTERNAL] Pfizer clinical trial did NOT report Maddie de Garay's result that she was paralyzed

Dear Janet,

Our staff is looking into this. We will keep you updated.

Best Regards,
Peter

-----Original Message-----
From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Sent: Friday, June 25, 2021 8:05 AM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>
Subject: FW: [EXTERNAL] Pfizer clinical trial did NOT report Maddie de Garay's result that she was paralyzed
Importance: High

More on this. jw

-----Original Message-----
From: Steve Kirsch <stk@m10.io>
Sent: Friday, June 25, 2021 1:10 AM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: [EXTERNAL] Pfizer clinical trial did NOT report Maddie de Garay's result that she was paralyzed
Importance: High

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She's still paralyzed. Has to eat via feeding tube. cannot walk on her own. She was in the Pfizer clinical trial in January.

You know this right?

-steve

From: Varnado, Martina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad1d1bc50f7941718b0feeb194cbaff1-Martina.Var]
Sent: 10/26/2021 12:10:38 PM
To: Russ, Wanda [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2900752acf81445785fb0f5b23c728c8-WRuss]
Subject: FW: [EXTERNAL] Clinical Trials of Covid-19 Vaccine for Children
Attachments: Letter to Federal Health Agencies Regarding Maddie and Clinical Trials for Children.pdf

Flag: Follow up

Please see the attachment as requested.

From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Sent: Friday, October 22, 2021 7:19 PM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>; Anderson, Steven <Steven.Anderson@fda.hhs.gov>
Cc: Varnado, Martina <Martina.Varnado@fda.hhs.gov>
Subject: FW: [EXTERNAL] Clinical Trials of Covid-19 Vaccine for Children

I know you have evaluated the case referred to in this letter. Janet W

From: Aaron Siri <aaron@sirillp.com>
Sent: Friday, October 22, 2021 5:21 PM
To: Mccluskie, Sean E (OS) <Sean.Mccluskie@hhs.gov>; Walensky, Rochelle P (CDC) <aux7@cdc.gov>; Shimabukuro, Tom (CDC) <ayv6@cdc.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Subject: [EXTERNAL] Clinical Trials of Covid-19 Vaccine for Children

Good afternoon,

Please see the attached letter regarding a serious injury suffered by a 12-year-old participant in Pfizer's Covid-19 vaccine clinical trial (out of around 1,100 children ages 12 to 15 that received this vaccine).

Before you move forward with EUA for 5- to 11-year-old children, please consider the attached and kindly require a properly powered trial to assess that the safety of the vaccine is greater than the likely harms to this age group by Covid-19.

Also, consider whether vaccinating children would increase the spread of SARS-CoV-2. As you know, the vaccinated can still become infected with and transmit SARS-CoV-2. Two recent studies, both of which have CDC scientists as authors, found that the vaccinated and unvaccinated both had at least the same rate of infection and viral load (and the asymptotic vaccinated had on-average a higher viral load). https://pubmed.ncbi.nlm.nih.gov/34351882/; https://www.medrxiv.org/content/10.1101/2021.07.31.21261387v4. *See also* https://pubmed.ncbi.nlm.nih.gov/34176436/; https://pubmed.ncbi.nlm.nih.gov/34596015/. Also, the official U.K. data shows that through September 2, 2021, a vaccine breakthrough rate for Delta infections of 23%. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1014926/Technical_Briefing_22_21_09_02.pdf. **Given the foregoing, will vaccinated children – who have immunity that reduces symptoms but leaves them able to still become infected with and spread the virus -- increase or decrease the spread of the virus?** (What if, because of linked epitope suppression, that adaptive immune response remains even after subsequent infection rendering them capable of repeatedly becoming infected with and transmitting the virus?)