6 April 2024

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Copied to:
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The Hon Mark Butler MP, Minister for Health and Aged Care.
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Re: Undisclosed Deaths in C4591001 Trial at the Vaccine and Related Biological Products Advisory Committee (VRBPAC) on December 10, 2020.

Dear Professor Lawler:

Thank you for your reply dated March 27, 2024.

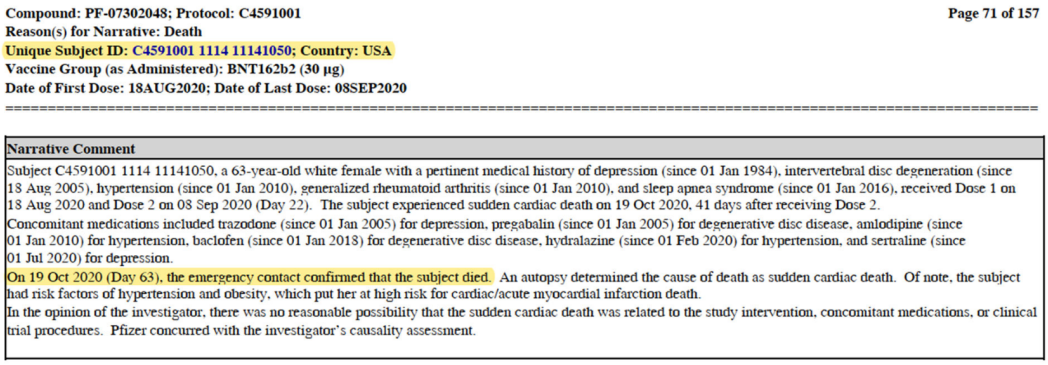
An essential aspect of pharmacovigilance involves continuously reassessing provided data. I wish to once again emphasise the two undisclosed deaths (that is, hidden deaths) at the time of considering Pfizer's COVID-19 vaccine emergency use authorization (EUA) in the United States in December 2020. The data that I highlight concerning timelines and date stamps may not have been available to the TGA at the time of Pfizer's December 2020 COVID vaccine EUA, but would have certainly been accessible from April 2021 onward at the issuance of the six-month safety report.

During its independent review of the data, the TGA team would have encountered the data I am about to discuss. I understand not all clinical trials can be audited extensively. However, because of the immense societal, economic, and psychological implications of the COVID-19 vaccination rollout, where people's livelihoods became dependent upon receiving the COVID-19 vaccine, the onus for ensuring data integrity would have been higher with the C4591001 trial.

At the six-month data review, the TGA team investigating the C4591001 trial data would have discovered a gross misrepresentation in the data presented to the public up to the data cut-off date of November 14th, 2020. Instead of the reported six deaths, with more deaths in the placebo arm (four deaths) compared to the vaccinated arm (two deaths), there were 11 deaths, with six deaths in the vaccinated arm compared to the five in the placebo arm. Though not statistically significant because of the small numbers involved, it would have been difficult to persuade the public to take a drug where more people died in the supposedly lifesaving intervention arm.

Subject 11141050 died on October 19th, 2020, well before the data cut-off date of November 14th, 2020. Documentation shows that the subject's emergency contact notified the clinical site of the death on the date of death, as per protocol requirements. The protocol also required the clinical site to notify Pfizer, via its vaccine SAE form, within 24 hours of receiving a death notification. However, the

clinical staff waited 37 days to enter this patient's death into Pfizer's records. Because of that delay, Pfizer did not submit this death as part of its EUA data, raising questions about the reasons for the delay and potential breaches of Good Clinical Practice.

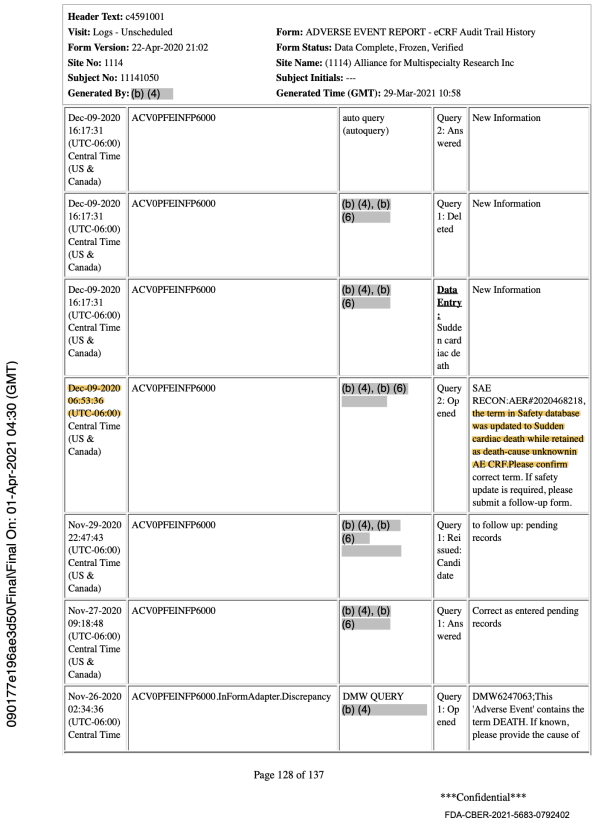


Compound: PF-07302048; Protocol: C4591001 **Page 71 of 157**
Reason(s) for Narrative: Death
Unique Subject ID: C4591001 1114 11141050; Country: USA
Vaccine Group (as Administered): BNT162b2 (30 µg)
Date of First Dose: 18AUG2020; Date of Last Dose: 08SEP2020

Narrative Comment
Subject C4591001 1114 11141050, a 63-year-old white female with a pertinent medical history of depression (since 01 Jan 1984), intervertebral disc degeneration (since 18 Aug 2005), hypertension (since 01 Jan 2010), generalized rheumatoid arthritis (since 01 Jan 2010), and sleep apnea syndrome (since 01 Jan 2016), received Dose 1 on 18 Aug 2020 and Dose 2 on 08 Sep 2020 (Day 22). The subject experienced sudden cardiac death on 19 Oct 2020, 41 days after receiving Dose 2. Concomitant medications included trazodone (since 01 Jan 2005) for depression, pregabalin (since 01 Jan 2005) for degenerative disc disease, amlodipine (since 01 Jan 2010) for hypertension, baclofen (since 01 Jan 2018) for degenerative disc disease, hydralazine (since 01 Feb 2020) for hypertension, and sertraline (since 01 Jul 2020) for depression. On 19 Oct 2020 (Day 63), the emergency contact confirmed that the subject died. An autopsy determined the cause of death as sudden cardiac death. Of note, the subject had risk factors of hypertension and obesity, which put her at high risk for cardiac/acute myocardial infarction death. In the opinion of the investigator, there was no reasonable possibility that the sudden cardiac death was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

Further inquiry is needed into the TGA's conclusion that this undisclosed death in the vaccinated arm was not due to the vaccine. On what basis was this determination made? This patient had an autopsy result that is not publicly available. If the TGA has access to this autopsy result, it would be in the public interest for it to be available for independent scrutiny.

Per the autopsy, the patient died from 'sudden cardiac death,' with her known risk factors of hypertension and obesity putting her at high risk of cardiac-acute myocardial infarct. The clinical site staff entered the specific diagnosis of 'sudden cardiac death' into her notes on December 9th, 2020, the day before the Vaccine and Related Biologicals Products Advisory Committee (VRBPAC) meeting on December 10th, 2020, which suggests that this hidden death also had autopsy results available at the critical juncture of consideration of vaccine emergency use authorization.



Header Text: c4591001
Visit: Logs - Unscheduled **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Frozen, Verified
Site No: 1114 **Site Name:** (1114) Alliance for Multispecialty Research Inc
Subject No: 11141050 **Subject Initials:** ---
Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 10:58

Dec-09-2020 16:17:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	New Information
Dec-09-2020 16:17:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Deleted	New Information
Dec-09-2020 16:17:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sudden cardiac death	New Information
~~Dec-09-2020 06:53:36 (UTC-06:00)~~ Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	SAE RECON:AER#2020468218, ~~the term in Safety database was updated to Sudden cardiac death while retained as death-cause unknownin AE CRF.Please confirm~~ correct term. If safety update is required, please submit a follow-up form.
Nov-29-2020 22:47:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Candidate	to follow up: pending records
Nov-27-2020 09:18:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Correct as entered pending records
Nov-26-2020 02:34:36 (UTC-06:00) Central Time	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW6247063;This 'Adverse Event' contains the term DEATH. If known, please provide the cause of

Page 128 of 137

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FDA-CBER-2021-5683-0792402

0901177e196ae3d50\FinalFinal On: 01-Apr-2021 04:30 (GMT)

https://www.phmpt.org/wp-content/uploads/2023/05/125742_S1_M5_CRF_c4591001-1114-11141050.pdf, p. 128

To be eligible for inclusion in this clinical trial, participants had to be deemed healthy based on medical history, physical examination (if required), and the clinical judgement of the investigator. The protocol allowed healthy participants with pre-existing stable disease – defined as disease not requiring significant change in therapy or hospitalization for worsening disease during the six weeks before enrolment – to participate in the clinical trial. I cannot find a blood pressure reading in her publicly available case notes. Consequently, I can only assume the patient's high blood pressure, from which she had suffered since January 1st, 2010, was well controlled when she was admitted to the trial.

The patient weighed 74.1kg at a height of 165cm. Hence, her BMI of 27.2 put her in the overweight category, not obese. Without reviewing autopsy results, does the TGA believe that such anthropometric readings put a person at high risk of sudden cardiac death? She died 41 days after Dose 2 of the vaccine. On what basis did the TGA discount this intervention as a cause of death?

Header Text: c4591001
Visit: V1_DAY1_VAX1_L
Form: VITAL SIGNS - BASELINE
Form Version: 30-Jul-2020 21:28
Form Status: Data Complete, Locked, Frozen, Verified
Site No: 1114
Site Name: (1114) Alliance for Multispecialty Research Inc
Subject No: 11141050
Subject Initials: ---
Generated By: (b) (4)
Generated Time (GMT): 29-Mar-2021 10:58

eCRF Audit Trail History

Vital Signs		
1.	Date:	Aug/18/2020
2.	Weight:	[74.1]
3.	Unit:	kg
4.	Height:	[165.0]
5.	Unit:	cm
6.	Body Mass Index:	[27.2]

Vital Signs Details		
7.a	Record Identifier:	1
	Temperature:	[37.4]
	Unit:	C
	Temperature Location:	ORAL CAVITY

https://phmpt.org/wp-content/uploads/2023/05/125742_S1_M5_CRF_c4591001-1114-11141050.pdf, p. 10

Subject 11201050 died on November 7th, 2020. Her husband reported her death to the clinical site on November 7th, 2020. Seventy-two days after receiving Dose 2 of the vaccine, she died in her sleep. No hospital visit or autopsy occurred. A coroner pronounced her death and listed the cause of death on her death certificate as cardiac arrest.

Compound: PF-07302048; Protocol: C4591001 **Page 75 of 157**
Reason(s) for Narrative: Death
Unique Subject ID: C4591001 1120 11201050; Country: USA
Vaccine Group (as Administered): BNT162b2 (30 µg)
Date of First Dose: 04AUG2020; Date of Last Dose: 27AUG2020

Narrative Comment
Subject C4591001 1120 11201050, a 58-year-old white female with a pertinent medical history of chronic back pain (since 2015), hypertension (since 2017), anxiety (since 2018), and type 2 diabetes mellitus (since 2018), received Dose 1 on 04 Aug 2020 and Dose 2 on 27 Aug 2020 (Day 24). The subject died of cardiac arrest on 07 Nov 2020, 72 days after receiving Dose 2. Concomitant medications included metformin (since 2017) for type 2 diabetes mellitus; lisinopril (since 2017) and clonidine (since 2018) both for hypertension; and lorazepam (since 2018) for anxiety. On 07 Nov 2020 (Day 96), the subject's husband notified the site that the subject had died in her sleep. The subject's husband reported that the night before her death, she had taken an unspecified muscle relaxant and diazepam (Valium) for her chronic back pain; these medications were previously used by the subject. No symptoms or illnesses leading to the subject's death were reported. The subject was not seen in the hospital. The coroner was called to pronounce death; an autopsy was not performed. On 04 Dec 2020 (Day 123), the subject's husband stated that the cause of death on the death certificate was cardiac arrest (also described as cardiopulmonary arrest). In the opinion of the investigator, there was no reasonable possibility that the cardiac arrest was related to the study intervention, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

https://phmpt.org/wp-content/uploads/2023/05/125742_S1_M5_CRF_c4591001-1120-11201050.pdf, p. 74

As no autopsy results were available, it remains unclear how the TGA concluded that this death could not be attributed to the vaccine. Would the TGA be similarly incurious for other 58-year-old women suddenly dying in their sleep after signing up for different experimental drug clinical trials? Pfizer documented receiving notification of her death on November 7th, 2020, well before the data cut-off date of November 14th, 2020. The reasons for not disclosing this death from the vaccinated arm at the December 10th, 2020, VRBPAC meeting or in the Polack *New England Journal of Medicine* publication need clarification.

I continue to highlight the hidden deaths in this trial to draw attention to a larger issue that my co-authors and I found in our forensic analysis peer-reviewed paper. Given the large number of clinical trial participants, the 38 deaths reported in the 6-Month Interim Report was surprisingly low (18% of the expected number). Did the TGA come to a similar conclusion in its scrutiny of the data? As of November 14th, 2020, 203 subjects had been lost to follow-up, (a higher number than the primary endpoint population of 170, from which the 95% efficacy claim came).

Additionally, delays in reporting the accurate date of subject deaths, known to Pfizer-BioNTech from the subjects' Narrative Reports, obscured the vaccine's cardiac adverse event signal. Adults aged 56 to 64 accounted for the first four deaths in the vaccinated arm of this trial. I have highlighted two of those patients, subjects 11141050 and 11201050, in this letter. Has the TGA investigated the clinical trial protocol violation of delayed death reporting in these cases?

I trust you agree that substantial safety reporting issues in this trial require further attention. I appreciate your ongoing correspondence and eagerly await your response to these concerns.

Yours sincerely,

Dr. Jeyanthi Kunadhasan
MD (UKM), MMed (AnaesUM), FANZCA MMED (Monash)