RE: FOI 24/204 follow on from FOI 24/075 - FOI request regarding subject 10841470 male 65, in the Pfizer trial.

FOILicensing <FOILicensing@mhra.gov.uk>
Mon 25/03/2024 15:46
To [redacted]
Cc:FOILicensing <FOILicensing@mhra.gov.uk>;MHRA Customer Services <MHRACustomerServices@mhra.gov.uk>

Dear [redacted]

Thank you for your request for information dated 28 February 2024, where you asked:

> "In view of your comments I would like to refine my request to the results of 2 of his immunogenicity blood tests.
> Blood was taken for these at visits 1 and 3 as per trial protocol on 30.9.2020 and 18.11.2020.
> The tests in question are likely to be SARS-CoV-2 N-binding antibody.
> A binary positive or negative for each test would suffice but the result may be presented in another way or another test may have been done in which case please supply the immunogenicity blood test results from those 2 days as they are stated.
>
> In the trial protocol the test is described as follows:
> Nonvaccine antigen (NVA) direct Luminex immunoassay.
> The NVA will include a SARS-CoV-2 target antigen that is not derived from the S glycoprotein, most likely an antigen derived from the SARS-CoV-2 nucleoprotein."

Our response
Initial searches of our records did not locate the requested information. Therefore, we contacted the Marketing Authorisation Holder (MAH) in relation to your request, and they have confirmed that "the results of the immunogenicity tests for Subject 10841470 taken on 30-Sep-20 and 18-Nov-20 were not listed in the Clinical Study Reports (CSRs) for the C4591001 study but instead these diagnostic data were provided to the [clinical trial] site as part of the Investigator Package". I have liaised with colleagues who have confirmed that we do not hold the investigator package in our records.

Advice and assistance
We advise contacting the MAH to request this information: Contact Us | Pfizer UK

Appeal rights
We hope that you will find the information you are seeking through onward contact with the MAH. However, if you disagree with how we have interpreted the Freedom of Information Act 2000 in answering your request, you can ask us to review our actions and decisions by writing to: info@mhra.gov.uk, and requesting an internal review.

Please note that your internal review request must be in a recordable format (email, letter, audio tape etc.), and that you have 40 working days upon receipt of this letter to ask for a review. We aim to provide a full response to your review request within 20 working days of its receipt. Please quote the reference number above in any future communications.

If you are not content with the outcome of the internal review, you would have the right to apply directly to the Information Commissioner for a decision. Please bear in mind that the Information Commissioner will not normally review our handling of your request unless you have first contacted us to conduct an internal review. The Information Commissioner can be contacted online via an electronic form: https://ico.org.uk/make-a-complaint/foi-and-eir-complaints/foi-and-eir-complaints/

Or in writing to:
Information Commissioner's Office,
Wycliffe House,
Water Lane,
Wilmslow,
Cheshire,
SK9 5AF

Yours sincerely,

HQA FOI Team

From: [redacted]
Sent: Wednesday, February 28, 2024 5:18 PM
To: MHRA Customer Services <MHRACustomerServices@mhra.gov.uk>
Subject: FOI 24/204 follow on from FOI 24/075 - FOI request regarding subject 10841470 male 65, in the Pfizer trial.

Dear MHRA Customer Experience Centre

Many thanks for your reply.

In view of your comments I would like to refine my request to the results of 2 of his immunogenicity blood tests.
Blood was taken for these at visits 1 and 3 as per trial protocol on 30.9.2020 and 18.11.2020.
The tests in question are likely to be SARS-CoV-2 N-binding antibody.
A binary positive or negative for each test would suffice but the result may be presented in another way or another test may have been done in which case please supply the immunogenicity blood test results from those 2 days as they are stated.

In the trial protocol the test is described as follows:
Nonvaccine antigen (NVA) direct Luminex immunoassay.
The NVA will include a SARS-CoV-2 target antigen that is not derived from the S glycoprotein, most likely an antigen derived from the SARS-CoV-2 nucleoprotein.

Many thanks for your help
Kind regards
[redacted]

Sent from my iPad

On 20 Feb 2024, at 17:31, MHRA Customer Services <MHRACustomerServices@mhra.gov.uk> wrote:

FOI 24/075

[redacted]

Thank you for your email.

Please find attached the response to your FOI request.

Kind Regards

MHRA Customer Experience Centre
Communications and engagement team
Medicines and Healthcare products Regulatory Agency
10 South Colonnade, Canary Wharf, London E14 4PU
Telephone 020 3080 6000

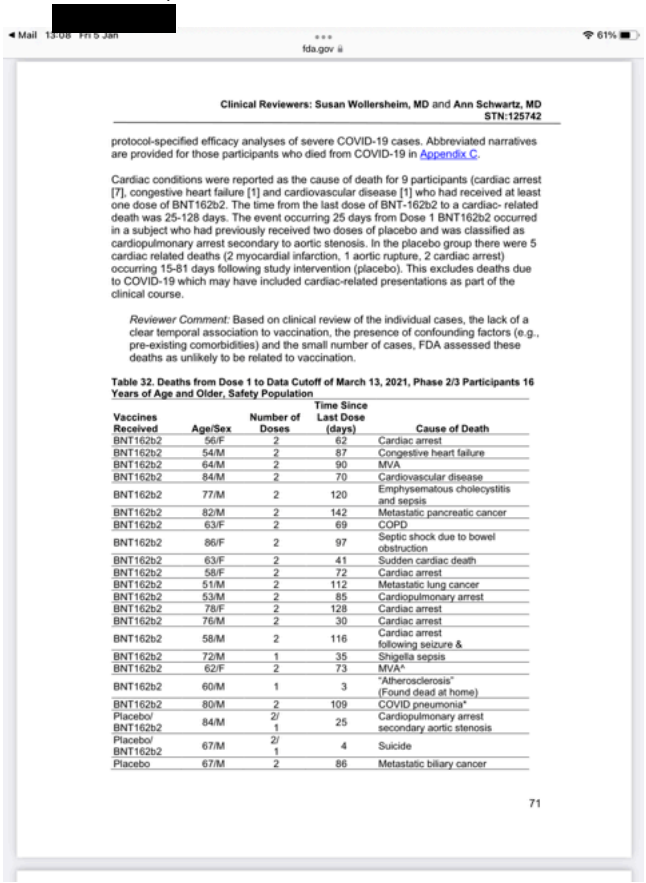
From: [redacted]
Sent: Tuesday, January 23, 2024 12:49 PM
To: MHRA Customer Services <MHRACustomerServices@mhra.gov.uk>
Subject: FOI 24/075 - RE: FOI request regarding subject 10841470 male 65, in the Pfizer trial.

[You don't often get email from [redacted] why this is important at https://aka.ms/LearnAboutSenderIdentification]

Dear MHRA Communications and engagement team,

Many thanks for your reply.
I much appreciate that you have explained the issues.
In view of what you have said, could you please send me the following:
1. The subjects narrative report.
2. Any tables you have tabulating deaths in the Pfizer trial similar to the two I enclose below (first page of each enclosed) complete with footnotes. The first is already available on the FDA website in a BLA Clinical Review Memorandum and the second is now available to the public at the US Public Health and Medical Practitioners for Transparency website after the intervention of a federal judge. The FDA's version of his narrative record is also available unredacted at that website (copy below). You do not need to add any participant number if it is not already in the table.
3. The results of his 2 antibody tests, blood was taken for immunogenicity at visit 1 on 30.9.20 and visit 3 on 18.11.20.

Many thanks for your help
Yours faithfully
[redacted]



◂ Mail 13:08 Fri 5 Jan
61%
fda.gov

Clinical Reviewers: Susan Wollersheim, MD and Ann Schwartz, MD
STN:125742

protocol-specified efficacy analyses of severe COVID-19 cases. Abbreviated narratives are provided for those participants who died from COVID-19 in Appendix C.

Cardiac conditions were reported as the cause of death for 9 participants (cardiac arrest [7], congestive heart failure [1] and cardiovascular disease [1] who had received at least one dose of BNT162b2. The time from the last dose of BNT-162b2 to a cardiac- related death was 25-128 days. The event occurring 25 days from Dose 1 BNT162b2 occurred in a subject who had previously received two doses of placebo and was classified as cardiopulmonary arrest secondary to aortic stenosis. In the placebo group there were 5 cardiac related deaths (2 myocardial infarction, 1 aortic rupture, 2 cardiac arrest) occurring 15-81 days following study intervention (placebo). This excludes deaths due to COVID-19 which may have included cardiac-related presentations as part of the clinical course.

Reviewer Comment: Based on clinical review of the individual cases, the lack of a clear temporal association to vaccination, the presence of confounding factors (e.g., pre-existing comorbidities) and the small number of cases, FDA assessed these deaths as unlikely to be related to vaccination.

Table 32. Deaths from Dose 1 to Data Cutoff of March 13, 2021, Phase 2/3 Participants 16 Years of Age and Older, Safety Population

Vaccines Received	Age/Sex	Number of Doses	Time Since Last Dose (days)	Cause of Death
BNT162b2	56/F	2	62	Cardiac arrest
BNT162b2	54/M	2	87	Congestive heart failure
BNT162b2	64/M	2	90	MVA
BNT162b2	84/M	2	70	Cardiovascular disease
BNT162b2	77/M	2	120	Emphysematous cholecystitis and sepsis
BNT162b2	82/M	2	142	Metastatic pancreatic cancer
BNT162b2	63/F	2	69	COPD
BNT162b2	86/F	2	97	Septic shock due to bowel obstruction
BNT162b2	63/F	2	41	Sudden cardiac death
BNT162b2	58/F	2	72	Cardiac arrest
BNT162b2	51/M	2	112	Metastatic lung cancer
BNT162b2	53/M	2	85	Cardiopulmonary arrest
BNT162b2	78/F	2	128	Cardiac arrest
BNT162b2	76/M	2	30	Cardiac arrest
BNT162b2	58/M	2	116	Cardiac arrest following seizure &
BNT162b2	72/M	1	35	Shigella sepsis
BNT162b2	62/F	2	73	MVA^
BNT162b2	60/M	1	3	"Atherosclerosis" (Found dead at home)
BNT162b2	80/M	2	109	COVID pneumonia*
Placebo/ BNT162b2	84/M	2/ 1	25	Cardiopulmonary arrest secondary aortic stenosis
Placebo/ BNT162b2	67/M	2/ 1	4	Suicide
Placebo	67/M	2	86	Metastatic biliary cancer

71

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16.2.7.7 Listing of Deaths – All S

Age Group (Years)	Subject	Dose No.	Rel Day[a]	Sex	Date of Death
16-55	C4591001 1021 10211127∞	2	88	M	19DEC2020
	C4591001 1081 10811194	2	37	F	04NOV2020
	C4591001 1120 11201266∞	2	113	M	19JAN2021
	C4591001 1127 11271112∞	2	86	M	04DEC2020
	C4591001 1152 11521085	1	8	F	26AUG2020
	C4591001 1156 11561124	2	32	M	02NOV2020
	C4591001 1229 12291083†	2	76	F	05JAN2021
	C4591001 1231 12314987	2	82	M	06DEC2020
>55	C4591001 1007 10071101∞	2	63	F	21OCT2020
	C4591001 1019 10191146	2	87	M	17DEC2020
	C4591001 1027 10271191#	2	135	F	13FEB2021
	C4591001 1036 10361140∞#	2	91	M	10FEB2021
	C4591001 1039 10391010∞	2	71	M	18NOV2020
	C4591001 1066 10661350	1	16	M	03NOV2020
	C4591001 1084 10841266∞	2	121	M	12JAN2021

Compound: PF-07302048; Protocol: C4591001 Page 43 of 15 43 of 3697
Reason(s) for Narrative: Death
Unique Subject ID: C4591001 1084 10841470; Country: USA
Vaccine Group (as Administered): Placebo
Date of First Dose: 30SEP2020; Date of Last Dose: 21OCT2020

Narrative Comment

Subject C4591001 1084 10841470, a 65-year-old white male with a pertinent medical history of hyperlipidemia and hypertension (since 2010) and pulmonary fibrosis (since 2014), received Dose 1 on 30 Sep 2020 and Dose 2 on 21 Oct 2020 (Day 22). The subject was diagnosed with COVID-19 infection and multiple organ dysfunction syndrome on 31 Dec 2020, 71 days after receiving Dose 2. On 23 Dec 2020 (Day 85), the subject received a prohibited vaccination (Moderna COVID-19 vaccine [mRNA-1273]) through his employer. The site was first informed of this vaccination by the subject's son on 07 Jan 2021 (Day 100).
Concomitant medications included ezetimibe/simvastatin (since 2010) for hyperlipidemia, omeprazole (since 2013) for gastroesophageal reflux disease, nebivolol hydrochloride (since 2015) for hypertension, and trazodone (since 2015) for insomnia.
The subject experienced shortness of breath, fever, cough, fatigue, and muscle aches "a day or so after" exposure to COVID-19 on 28 Dec 2020 (Day 90). On 31 Dec 2020 (Day 93), the subject received monoclonal antibodies from his primary care physician. Later the same day (Day 93), the subject presented to the emergency department with weakness, dyspnea, nausea, and diarrhea and was subsequently hospitalized with COVID-19. On the same day (Day 93), the subject's laboratory tests included: a positive SARS-CoV-2 test, sodium of 134 mmol/L (normal range [NR]: 137-145 mmol/L), chloride of 97 mmol/L (NR: 98-107 mmol/L), glucose of 121 mg/dL (NR: 74-99 mg/dL), aspartate aminotransferase of 78 (NR: 17-59, unit not provided), alanine aminotransferase of 51 (normal high: 50, unit not provided), C-reactive protein of 191.2 mg/dL (normal high: 10 mg/dL), total protein of 8.5 g/dL (NR: 6.3-8.2 g/dL), D-dimer quantitative of 1.21 µg/mL fibrinogen equivalent units (normal high: 0.50 µg/mL), red blood cell count of 5.86 M/mm3 (NR: 4.20-5.70 M/mm3), hemoglobin of 17.8 g/dL (NR: 13-17 g/dL), and hematocrit of 53.1% (NR: 40%-50%). The chest x-ray that same day (Day 93) was consistent with bilateral multifocal viral pneumonia. The subject was treated with ondansetron hydrochloride, dexamethasone, sodium phosphate, enoxaparin sodium, nebivolol hydrochloride, magnesium sulfate, trazodone, acetaminophen, magnesium oxide, potassium bicarbonate/citric acid, potassium chloride, pantoprazole, loperamide, melatonin, and vitamin D3. On 02 Jan 2021 (Day 95), the subject was treated at bedside for acute hypoxemic respiratory failure with a left radial arterial line placed, and he was intubated. After being placed on a ventilator, his health status continued to deteriorate, resulting in multiple organ dysfunction syndrome. On 04 Jan 2021 (Day 97), he suffered acute renal failure. Acute hypoxic respiratory failure and acute renal failure were considered because of the COVID-19. On 11 Jan 2021 (Day 104), the subject's family opted for "do-not-resuscitate" status. On 19 Jan 2021 (Day 112), the site learned that the subject had died on 11 Jan 2021 (Day 104), and it was unknown if an autopsy was performed. It was reported that the subject also experienced shock, nose bleeding, pulmonary fibrosis, hypertension, acute kidney injury, dyslipidemia, and gastroesophageal reflux disease. The cause of death was reported as disease progression, multiple organ dysfunction syndrome, and COVID-19 infection.
The subject's vaccine status was unblinded on 14 Jan 2021.
In the opinion of the investigator, there was no reasonable possibility that the COVID-19 infection and multiple organ dysfunction syndrome were related to the study intervention, concomitant medications, or clinical trial procedures. Multiple organ dysfunction syndrome was considered related to COVID-19. Pfizer concurred with the investigator's causality assessment.

PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:24) Source Data: dm, vs, mh, ex, ae, cm, ds Output File: ./nda2 unblinded/C4591001 BLA Narrative Safety/profile Date of Generation: 01APR2021 (10:49)

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> On 15 Jan 2024, at 10:33, MHRA Customer Services <MHRACustomerServices@mhra.gov.uk> wrote:
>
> FOI 23/972
>
> Dear [redacted]
>
> Thank you for your request for information dated, Tuesday December 12, 2023, where you asked:
>
> "I would be grateful if you would send me all of the information you hold on the following Pfizer trial participant. He is the placebo group participant who died on 11.1.2021 after having one dose of Moderna COVID-19 vaccine on 23.12.2020, via his employer.
> Please include any tables that his death is recorded in. His death was one of the 38 deaths that occurred between dose 1 and the data cutoff of 13.3.2021 and one of the 29 deaths that occurred during the blinded, placebo-controlled part of the study, so please include any tables relating to these deaths.
>
> Participant.....10841470 male 65
>
> Study sponsor.....BioNTech
> Study conducted by.....Pfizer
> Study intervention number.....PF07302048
> Study intervention name.....RNA-Based COVID-19 Vaccine Protocol number.....C4591001
> Phase.....1/2/3
> Short title:
> A Phase 1/2/3 Study to Evaluate the Safety, Tolerability and Efficacy of RNA Vaccine Candidates Against COVID-19 in Healthy Individuals."
>
> Our response:
> We wish to inform you that we want to be as open as possible in answering requests or information. We can confirm that MHRA does hold some information within scope of your request. However, your request is very broad primarily due to the terminology used 'all information' ... about a specific trial participant. After preliminary searches we have established that gathering all the information we hold on this participant, as per the requirements of the FOIA, would exceed the limits under Section 12 of the FOIA. We have reached this conclusion because:
>
> * The term 'all' would require us to conduct an expansive search through the clinical study report, associated annexes, possibly assessment reports, and also any other material where this participant may be cross-referred to.
> * Two members staff have spent significant amounts of time locating information in preliminary searches.
> * While the participants death will be recorded in tables in the clinical study report this will be not be linked with the subject number-which in this document will appear on a separate page. Therefore, the cause/s of death and other details would need to be manually cross-referenced to other relevant tables in the clinical study report.
> * Clinical trial information has been submitted in tranches throughout the lifecycle of the vaccine.
>
> Section 12(1) of the FOIA allows MHRA to refuse a request for information if we estimate that the cost of complying with the request would exceed the appropriate fees limit for determining whether we hold the information, and in locating, retrieving and extracting the information. Whilst we have located some of information within scope of your request, it has become clear that the cost limit would be exceeded by a complete search as set out in section 12(1) of the FOIA and we have therefore ceased any further searches. Section 16 of the Freedom of Information Act requires MHRA to provide advice and assistance to the requestor, and this is provided below.
>
> Advice and assistance
> If you wish to submit a narrowed request, we would suggest requesting the participant's narrative of death which in the adjacent pages is accompanied by tables of the participants biometric information. However, we would like to advise that FOI is a disclosure to the world and on receipt of a narrowed request, we will need to consider whether any exemptions under the FOI apply - we'd therefore like to make you aware that health information relating to deceased individuals may be covered by section 41 (information provided in confidence).
>
> If you wish, it may be an option for you to approach the Marketing Authorisation Holder (MAH) with your enquiry directly: Contact Information for Healthcare Professionals | Pfizer Medical Information - UK
>
> We trust that you will find our response acceptable. However, if you disagree with how we have interpreted the Freedom of Information Act 2000 in answering your request, you can ask us to review our actions and decisions by writing to: info@mhra.gov.uk, and requesting an internal review.
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> Please note that your internal review request must be in a recordable format (email, letter, audio tape etc.), and that you have 40 working days upon receipt of this letter to ask for a review. We aim to provide a full response to your review request within 20 working days of its receipt. Please quote
> the reference number above in any future communications.
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>
> Or in writing to:
> Information Commissioner's Office,
> Wycliffe House,
> Water Lane,
> Wilmslow,
> Cheshire,
> SK9 5AF
>
> Yours sincerely,
>
>
> MHRA Customer Experience Centre
> Communications and engagement team
> Medicines and Healthcare products Regulatory Agency
> 10 South Colonnade, Canary Wharf, London E14 4PU
>
>
> -----Original Message-----
> From: [redacted]
> Sent: Tuesday, December 12, 2023 1:36 PM
> To: MHRA Customer Services <MHRACustomerServices@mhra.gov.uk>
> Subject: FOI request regarding subject 10841470 male 65, in the Pfizer trial.
>
> [You don't often get email from [redacted] Learn why this is important at https://aka.ms/LearnAboutSenderIdentification]
>
> Dear Sir or Madam,
>
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> Participant...............................10841470 male 65
>
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> Study intervention name........RNA-Based COVID-19 Vaccine Protocol number.....................C4591001
> Phase.......................................1/2/3
> Short title:
> A Phase 1/2/3 Study to Evaluate the Safety, Tolerability and Efficacy of RNA Vaccine Candidates Against COVID-19 in Healthy Individuals.
>
> Many thanks for your help
> Yours faithfully
> [redacted]
>
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>
> DISCLAIMER This email and any files transmitted with it are confidential. If you are not the intended recipient, any reading, printing, storage, disclosure, copying or any other action taken in respect of this email is prohibited and may be unlawful. If you are not the intended recipient, please notify the sender immediately by using the reply function and then permanently delete what you have received. Incoming and outgoing email messages are routinely monitored for compliance with the Department of Health's policy on the use of electronic communications. For more information on the Department of Health's email policy, click DHTermsAndConditions<https://www.gov.uk/help/terms-conditions>

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